Project Title: Community Active and Healthy Families: Family-Centered Obesity Treatment for Latino Children
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I. HYPOTHESES AND SPECIFIC AIMS:

This Human Subjects Research involves a pilot trial using a pre/post design to simultaneously to evaluate the feasibility, acceptability, and preliminary effectiveness of a weight management intervention, Community Active and Healthy Families (Community-AHF), at reducing child body mass index (BMI).

Study Aim : To pilot Community-AHF among 5–12-year-old overweight and obese Latino children in immigrant families (n=40 parent/child dyads) using a pre/post design

- We will examine changes in child BMI (primary outcome) and in diet, physical activity, and parenting skills/stress (secondary outcomes) pre- and post-intervention to assess for indicators of intervention effectiveness and to gather the information needed to refine measures, and measurement procedures in preparation for a pragmatic randomized controlled trial.
- We will evaluate pilot implementation via assessing program acceptability and feasibility. We hypothesize that families will report high levels of program acceptability and that implementing community organizations/clinics will report high levels of program feasibility and an intention to maintain participation in a future trial. We will also conduct qualitative interviews to explore implementation successes and challenges to guide refinement of implementation protocols for a future trial.

II. BACKGROUND AND SIGNIFICANCE:

Effective, family-oriented childhood weight management interventions for Latinos are critical in order to decrease lifetime cardiovascular disease (CVD) risk that stems from childhood obesity. Childhood obesity is a risk factor for adult CVD, the leading cause of death in the US.[1,2] One in four US children is Latino and Latino children have among the highest childhood obesity rates of any racial/ethnic group.[3-5] US-born Latino children of immigrant parents comprise half of US Latino children and experience higher obesity rates than other Latino children.[6,7] Obesity rates among Latino children have increased during the COVID-19 pandemic.[8] In parallel with obesity prevention efforts, a specific focus on treatment is urgently needed.

Implementation of current US Preventive Services Task Force (USPSTF) recommendations for childhood obesity has the potential to exacerbate existing disparities for Latino children in immigrant families**.** The USPSTF recommends referral of all children with obesity to an intensive weight management program to prompt behavior changes to decrease body mass index (BMI).[9] Intensive programs are found mainly in clinical settings, are limited in number and frequently are not feasible for Latino immigrant families.[10,11] Sustaining participation of Latino immigrant families in intensive community-based programs has been difficult due to the time commitment required and cultural and language barriers.[12,13] Reducing obesity disparities for Latino children in immigrant families requires addressing the current lack of evidence-based obesity treatment programs that are tailored to their sociocultural needs and delivered at a feasible intensity.

We propose addressing this gap with the Community-Active and Healthy Families (Community-AHF) intervention. Community-AHF is a behavioral-theory based, culturally tailored, Spanish-language weight management program for overweight/obese Latino children and their families. Community-AHF has recommended USPSTF components of intensive weight management delivered at a feasible intensity for low-income families.[9] To create Community-AHF, we engaged partners to complete Intervention Mapping to adapt an evidence-based weight management intervention designed for low-income Latino children in immigrant families delivered in healthcare settings.[14-16] Community-AHF retains key components of the original intervention and responds to feedback from Latino immigrant families that delivery in a community setting is preferable to a clinic due to easier access to and greater trust and familiarity with community organizations.

Intervention delivery in a community setting requires critical attention to how this change in delivery setting may impact intervention components and their implementation. We engaged key partners using community-based participatory research (CBPR) principles to identify adaptations of Clinic-AHF to allow for community delivery via a systematic process, Intervention Mapping-Adapt.[15] This process has been used successfully in adapting and implementing health interventions among immigrant Latinos in the US.[17-19] Use of this process ensures that Community-AHF retains Clinic-AHF essential components while incorporating adaptations required of the new delivery setting. While Intervention Mapping-Adapt was the appropriate element of Intervention Mapping for adaptation, Implementation Mapping, is the right process to ensure "how" the core components of the intervention are delivered meets partners' needs and priorities.[15,20]

II. RESEARCH METHODS

A. OUTCOME MEASURE(S):

Change in child body mass index, diet, physical activity, obesogenic food availability in the home, parent physical activity

promotion, parenting self-efficacy, parent perceived stress, intervention acceptability, feasibility, intervention fidelity

B. DESCRIPTION OF POPULATION TO BE ENROLLED:

Community-AHF Pilot enrollment is for six (6) months. For this part of the study, we will be relying on primary care referrals or community based referrals.

- Inclusion Criteria: 1) Child aged 5-12; 2) Child BMI > 85th %tile; and 3) Parent self-identifies as foreign-born Latino/Hispanic and speaks Spanish.
- Exclusion Criteria**:** Child medical contraindication to diet/PA modification and Child BMI ≥40kg/m^2 (obesity this severe needs subspecialty management)

C. STUDY DESIGN AND RESEARCH METHODS:

***Study Design*:**

We will recruit child-parent dyads from one primary care pediatric practice in both CO and MD or via outreach by our community partner in CO. We will recruit 20 child-parent dyads at each site. We will enroll 40 overweight (BMI≥85th%ile for age and sex) or obese (BMI≥95th%ile for age and sex) 5–12-year-old patients and a parent/guardian. We will examine changes in the anticipated trial outcomes. We will assess intervention acceptability and feasibility to parents and examine preliminary effectiveness. The primary effectiveness outcome will be a change in BMI from baseline to follow up. Secondary outcomes reflect key features of the intervention curriculum that promote child and family behavior change including child diet and PA, home food environment, parent PA promotion and parenting self-efficacy. We will also conduct a preliminary implementation evaluation. If two (2) children in the same household are eligible, one will be randomly selected to be in the index child participant.

Community AHF is a 10-month intervention with 20 contact hours (16 in person during the active phase and 4 virtual during the maintenance phase). Each index child participant must be accompanied by a parent; additional parents/caregivers and siblings of the index child may attend. This pilot will evaluate the active phase of the intervention *only* given the time constraints of this funding mechanism. Effectiveness data for the evidence-based intervention from which Community-AHF was adapted is based on the 4-month active phase.[14] During the 4-month active phase participants attend eight 2-hour semimonthly group education sessions. Sessions follow a curriculum and provide: 1) Practical information to increase knowledge and perceived importance of healthy diet and PA practices; 2) Skill building in problem-solving and positive parenting to overcome barriers to behavior change at the child and family-level; 3) PA; and 4) Facilitated supportive discussion to assist parents in managing stressors and SDOH barriers to healthy weight.

Each session covers specific objectives and includes complementary hands-on activities and breakout groups for children (children's breakouts are often conducted in English). At the conclusion of each session participants receive take-home materials to facilitate behavior change. Sessions are co-facilitated by a registered nurse and CHW. Additionally, participants complete 7 CHW coaching calls (15-20 minutes) during weeks without a group session to reinforce change goals and discuss successes and challenges meeting these goals. During the 6-month maintenance phase which will be employed in a future trial, participants will complete monthly, 20-minute coaching calls, attend a primary care obesity follow-up visit, and attend a concluding celebration. Community-AHF will be delivered by trusted community organizations well-known to the local Latino community and experienced in providing community programming.

We will also complete a qualitative evaluation of the Community-AHF pilot and its implementation. We will interview a subset of parents and youth who participate in the intervention for this portion. These interviews will take place after the completion of the pilot.

Retention –

Strategies include: 1) obtaining multiple methods of contact with updates at each point of contact with the study team and obtaining permission to extract contact information from the child's electronic health record; 2) establishing loss to follow-up protocols using multiple contacts for each method of participant contact; 3) creating a study identity through use of a logo and consistent fonts and colors on all study materials; 4) employing bilingual staff skilled at building relationships with immigrant study participants; 5) offering remuneration for participation in data collection; and 6) scheduling data collection visits based on participant preference including evenings and weekends.

Consent –

Owing to the characteristics of our study population, we expect to utilize Spanish-language consent forms for parents and need to account for limited literacy of participants. We will utilize an informed consent process that we have previously found effective with the proposed study population. The research staff member will read the Spanish-language form aloud while the participant follows along with their own hardcopy, elicit, and respond to participant questions, and finally ascertain understanding via 2-3 brief questions (e.g., Will participants in the Community-AHF program complete surveys?) Participants will have as much time as necessary to review the consent form and ask questions.

We will complete an assent process for children ≥7 years of age participating in the Community-AHF pilot. A research staff member will discuss the research with the child in the presence of the child's parent or guardian. The assent process will discuss the purpose of the research study, what the participants would have to do in the research study, associated risks and benefits and emphasize that the participation is voluntary. We will have the child provide verbal assent, and this assent will be noted on the parent's consent form.

Signed consent forms will be kept in a locked file cabinet in a locked office. Participants will be provided with a copy of the consent form for their reference.

Additionally, we are requesting a waiver of consent and HIPAA authorization for the screening used to determine eligibility for children for the Community-AHF program.

Renumeration –

Participants in the Community-AHF pilot will receive the following remuneration:
Survey-Baseline ($75)
Survey-Follow Up (4 months after baseline) ($75)
Accelerometer-Baseline ($50)
Accelerometer-Follow Up ($50)
Follow-up Interview-Parent ($50) and Follow-up Interview-Youth ($25)

***Research Methods*:**
Pilot dyads will complete the active phase of the Community-AHF intervention that includes eight (8), semimonthly 2-hour group education sessions for 16 weeks, and 8 biweekly coaching calls. Sessions follow a curriculum and provide: 1) Practical information to increase knowledge and perceived importance of healthy diet and physical activity practices; 2) Skill building in problem-solving and positive parenting to overcome barriers to behavior change at the child and family-level; 3) Physical activity; and 4) Facilitated supportive discussion to assist parents in managing stressors and social determinants of health barriers to healthy weight. Each session covers specific objectives, includes a number of complementary, hands-on activities, and provides participants with take-home materials to facilitate behavior change. Community-AHF will be delivered by a nurse and a Community Health Worker (CHW) trained by a consultant nutritionist and study investigators.

If the child has been referred by their pediatrician referring providers will also receive a communication regarding the family's participation. Once the child starts a cohort there will be an additional communication to the referring provider when the child completes the 4-month active phase. This communication will include a summary of family goals for healthy child weight, the current BMI, and a reminder that the child should have a follow up visit with the referring provider. The consent process will include specific permission for this release of information to the referring provider and/or signing of a separate release of information of form based on IRB determination.

Parent-completed surveys during home visits will include information on parent, child and family sociodemographic characteristics, covariates of interest (e.g., child sleep and screen media use) and scales/measures used to determine secondary outcomes. Family sociodemographic characteristics will be measured at baseline only. The follow-up survey will include brief measures of satisfaction with the Community-AHF intervention, acceptability and feasibility. Parent-completed surveys will be administered via guided oral administration by the research staff member and all answers will be entered directly into a REDCap electronic survey form to allow for simultaneous data capture and storage. The exception to this is the responses to the secondary outcome diet measure (Block Hispanic Food Frequency Questionnaire) which will be entered into a proprietary web interface provided by NutritionQuest. We have used guided oral administration in our past research with similar study populations to allow for survey completion by populations with limited literacy and who may be unfamiliar or uncomfortable with electronic survey formats. Participants will be given the option to complete the survey on their own via a study computer with the research staff member present.

Another data component of the home visits is a home food inventory that will be completed by the research staff members by visualizing food stored in the home and recording types of food and quantity. The parent completing the survey will guide the research staff member to food stored in the home. The research staff will record responses and home food inventory information into the REDCap electronic survey. The research staff member will also complete anthropometric measurements to calculate BMI by twice measuring height to the nearest 0.1cm and weight (light clothing, no shoes) to the nearest 0.1kg using stadiometers (Hopkins Road Rod) and portable digital scales (Seca 874), respectively. All anthropometric measurements will be recorded in REDCap by the research staff member. In lieu of a home visit, participants can complete data collection visits in a private space at either of the research institutions involved in the proposed work or at the community organization.

Regarding physical activity measurement using accelerometers, research staff will provide the index parent/child dyad with a ActiGraph GT9X Link accelerometer at each data collection home visit and instruct them to have their child to wear it like a watch on the non-dominant wrist for seven consecutive days and nights and to remove it only for aquatic activities (e.g., swimming, bathing) and group sports that prohibit wearing jewelry or watches (e.g., basketball, soccer). Study staff will provide participants with contact information for any questions/concerns about the accelerometer. After 7 days, participants will return the accelerometers to the community organization involved in the study or via prepaid protective envelopes based on participant preference. After receiving the device, research staff will wipe it with the alcohol disinfecting cloth, download the data and set it up for redistribution to the next participant.

D. RISKS AND BENEFITS:

The risks of anthropometric measurements are discomfort and emotional upset. For accelerometry in particular there may be a perceived risk of external monitoring or "tracking". Accelerometer data is not generated through real-time tracking and the location of participants is not recorded by the device. Data collected by the accelerometer can only be accessed when the device is returned and accessed via specialized proprietary software. If the device is lost or stolen, it is extremely unlikely that data could be accessed. If accessed, participant information other than activity data would *not* be available. The only risk of the surveys and of EHR data extraction is breach of confidentiality. The risk of the home visit for data collection is breach of confidentiality and discomfort with having study staff enter the home. Breach of confidentiality will be strictly guarded against, and any unintentional breach of confidentiality would not be anticipated to affect the employability, reputation, or financial status of a participant.

The primary risk of follow-up interviews is breach of confidentiality and will be strictly guarded against, and any unintentional breach of confidentiality would not be anticipated to affect the employability, reputation, or financial status of a participant. Additionally, participants may also feel uncomfortable providing negative feedback about Community-AHF or its implementation.

Protection Against Risk – The primary risk across all aims is breach of confidentiality. We will ensure that personally identifiable information, including lists of potential participants, will be stored in secure environments. Documents, interview transcripts and survey data will be stored in locked file cabinets and data will be stored on secure computers protected by University of Colorado (CU) and Johns Hopkins University security protocols. Both institutions have state-of-the-art information technology to assure high security in data storage and transfer. No identifiable data will be stored on personal computers or devices. The proposal will be reviewed and approved by COMIRB prior to any work being done. We will take the following additional steps to protect privacy and confidentiality:

- Only the study team will have access to identifying information.
- Each study participant will be assigned a unique identification (ID) number at the time of recruitment to de-identify their name from data. The database linking the ID with the participant will only be accessible to select research staff (Multi-PI, site research coordinator, data manager)
- Audio files will be uploaded within 24 hours to a secure network drive that is password protected and backed up regularly.
- After uploading the audio file, it will be deleted from the recorder.
- Once transcribed by professional transcription services that meet HIPAA privacy and confidentiality standards, textual data will be uploaded to this same server and only analyzed from password-protected devices that can access this server.
- For the surveys, individual subjects' survey responses will be confidential through the use of REDCap.

Benefits – There are many potential health benefits to participants in endeavoring to reduce child BMI, including lower adult cardiovascular disease risk. Although past research has demonstrated benefit from receiving the type of intervention that we will deliver in this trial, confirmed benefit from participating in this research cannot be claimed, as we are testing an adaption of an evidence-based intervention in new communities. Regardless of intervention effectiveness, the potential benefits for the study participant include receiving information regarding healthy behaviors and positive parenting skills. Given that the risks are minimal and the potential for positive health benefits, we believe that the benefits of the proposed project far outweigh any risks.

E. POTENTIAL SCIENTIFIC PROBLEMS:

Likewise, some dyads will not wish to complete all aspects of the pilot study. We will work with families to complete measures that they feel comfortable with. Acceptance or denial of study procedures will provide important information for a future larger scale trial.

F. DATA ANALYSIS PLAN:

Indicators of Effectiveness

As this is a pilot study, we will not be powered to detect statistically significant differences pre- and post- intervention. We will measure the average change in $\%BMI_{p95}$ between baseline and completion of the Community-AHF active phase. Without a counterfactual (control group) we will not be able assign responsibility to Community-AHF for any observed

improvements. Change in $\%BMI_{p95}$ across the study period will provide data to test our hypotheses and will inform statistical power analyses for a subsequent trial. This pre- and post-intervention data is ideal for generating sample size estimates for a larger randomized control trial in the same population.

We will conduct within-individual analyses for each outcome of interest. We will only analyze participants who contribute pre and post measures in order to avoid biases that can occur when analyses are conducted with all available data. For each outcome for which a participant contributes pre and post measurements, we will calculate pre and post means, standard deviations, differences in means and the p-value of the difference. We will conduct preliminary analyses of outcomes according to subgroups defined by rate of attendance at intervention sessions. If adequate data are available, we will explore the possibility of a nonresponse analysis.

All statistical analyses will be conducted using Mplus, or the latest version of R (specifically the nlme package).[21]

Preliminary Implementation Evaluation

Survey measure results will be summarized using descriptive statistics. Qualitative data from follow-up interviews will be analyzed using rapid qualitative methods as we anticipate a short time frame between obtaining these data and refinement of the implementation protocol in preparation for a future trial if funded. Interview transcripts will be summarized in a template based on the guiding questions to capture key points. Summarizing will be completed by the research team who will resolve differences through consensus. Using matrix analysis techniques[22], summaries will be categorized by site and participant type (parent, child or community organization staff member). Two research team members will independently identify and group key themes from summaries, and then compare themes. Finally, a saturation grid[24], which visually aligns support for themes, will be developed to cross-check and confirm evidence of themes against the dataset.

Data Management – Audio recordings will be stored in a UC-Anschutz secure encrypted database. REDCap will serve as the storage system for surveys. Only the PI, data analysts, and research staff will have access to the data. All identifiable information will be restricted for contact information only and will be separated from other study data. All identifiable information will be removed from audio recordings and survey data. Consent forms will be stored in a locked cabinet at the sites ACCORDs for Aurora Community Connection and Johns Hopkins Bayview Medical Center, MD. Due to the nature of the pilot, consent forms will be transferred from the home of the participant to the site. In these cases, the consent forms will not be left unsupervised during transport and will be placed in a locked cabinet immediately upon reaching the site destination. Research staff will minimize additional trips to obtain consent from participants in order to safeguard confidentiality.

Date Destruction – Paper consent forms and data stored on servers will be destroyed per HIPAA regulations (7 years after IRB of record acknowledges study closure).

G. SUMMARIZE KNOWLEDGE TO BE GAINED:

The findings from the proposed research will directly impact pediatric primary care practice and treatment of child obesity. This proposed study will answer a pivotal question about whether community-based weight management can successfully reduce overweight and obesity among Latino children. Overall, the knowledge to be gained by this study is valuable enough that the minimal risks of the study are reasonable in relation.

H. REFERENCES:

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