Protocol, Version #10

Title: Adapting Diet and Action for Everyone (ADAPT+) Study Protocol and Statistical Analysis Plan.

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Study Title: ADAPT+: Optimizing an Intervention to Promote Healthy Behaviors in Rural, Latino Youth with Obesity and their Parents, using Mindfulness Strategies.

Proposal # #Pro00039979

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Guidelines for studies meeting the criteria for expedited or full Board review:

A. Overview:

1. Rationale for the study, area of current scientific concern and why the research is needed;

Rates of obesity among Latino youth is increasing exponentially.[1-4] It is estimated that unless this trend is reversed, 90% of US-born children of Mexican immigrants will be of overweight or obese status by 2030,[5] particularly those living in rural communities.[6-10] With a rise in obesity, Latino youth are at increased risk for metabolic syndrome, type 2 diabetes, cardiovascular disease and cancer.[11-14] Lifestyle interventions have predominantly depended on education and cognitive-behavioral strategies to improve diet and physical activity (PA), with parent- focused interventions showing the most consistent success for youth.[15,16] Still, these studies often produce only modest and short-term results.[17] The link between parent stress and offspring obesity has been shown,[18] yet the role of parent stress on obesity has not been well addressed in interventions for reducing obesity in Latino youth. Evidence implicates stress in disordered eating and obesity[21,22] and parent stress relates to risk factors for childhood obesity.[18] Mindfulness-based programs are successfully delivered to low-income, minority, public school students;[23] however, few studies target Latino families.

2. Living in a rural community compounds the health care disparity of Latino youth and obesity.

Most Latinos in Florida (outside of Miami) live in rural areas and work as migrant farmworkers.[10,32] Latino youth living in rural areas are 25% more likely to have overweight/obesity than Latinos in urban areas.[7,10] Compared with Latinos living in urban areas, Latinos in rural areas typically consume more meals with friends and relatives outside the home, making food choices more difficult. Lack of access to affordable, healthy foods; few community resources; acculturation-related dietary changes (e.g., eating more processed and fast foods[31]) and poverty are key contributing factors to obesity.[7-9] Children in households living below the poverty line have 243% higher odds of developing childhood obesity than children living above the poverty threshold.[10,32,33] Latino rural communities have been largely ignored despite the rising economic, social, and personal burden of obesity, including medical care costs.[34,35]

3. Link between Latino parent stress and offspring obesity.

A growing body of evidence implicates stress in obesity,[21,22] especially related to food choices and preferences.[36] An American Psychological Association survey reported 39% of adults overeat or increase intake of calorie-dense foods in response to stress.[21] Moreover, inability to maintain improvements in healthy lifestyle behaviors is linked with psychological distress in individuals with obesity.[37] In youth, chronic stress has been linked with larger waist circumference and BMI.[38] Latino families are especially subject to specific and burdensome stressors (e.g. economic hardship and fear of family member deportation) that may predispose them to behaviors that increase obesity. The large scale "SOL" investigation of Latino youth and their caregivers (n=473; children aged 8–16 years) found the incidence of youth obesity

increased substantially with the number of caregiver stressors.[18] Long work hours, common among migrant worker families, can reduce parent involvement, including uninvolved feeding style, which can increase risk of obesity in youths.[39,40] Specifically, parent stress is associated with decreased physical activity (PA), overeating[41] and higher body weight in both children and parents.[42] Given the literature that highlights the importance of focusing on parents in changing eating, PA and other health behaviors in youth, targeting parent stress to impact these behaviors may be key.[15,16] However, there is a lack of culturally competent, evidence-based, interventions to address stress and its concomitant relation with the urgent public health issue of overweight/obesity among rural Latino youth.[35]

4. Critical barriers to progress in the field:

Most obesity interventions for Latino youth report mixed findings, are small in scope and exploratory[28,43,44] and fail to incorporate key factors important for Latinos living in rural communities.[17,31,44,45] For example, community-based interventions promote better 'buy-in' from Latino families,[17,28,44] particularly utilization of promotoras (community health workers),[29] yet most available studies have not delivered interventions in a community setting.[46] Moreover, the "state of the obesity intervention field" suggests that interventions that are parent-focused, but also involve the entire family, show the most promise.[16] This is particularly the case in Latino families because of the strong commitment to the family system ("familismo"), yet most extant studies involving Latinos do not include children. The majority of studies also have lacked: rigorous experimental methodology, manualized treatment programs that measure both physical activity (PA) and eating behaviors, culturally appropriate strategies,[31,44,45] and longitudinal follow-up assessments.[17] To date, obesity interventions with Latinos have also lacked sufficient attention to barriers to success, including acculturation considerations which include, dietary changes such as, using larger quantities of sodium, oils, and sugars; consuming an excess of sugar-sweetened beverages and fast food; and having a suboptimal consumption of fruits and vegetables.[17,48-56] We argue here that mixed results of interventions may also be due to their failure to successfully address multi-faceted psychosocial risk factors, such as parent stress.[57] Multifaceted approaches must be taken into consideration in designing intervention strategies to increase the effectiveness and sustainability of health behavior changes for migrant Latino families. In response to these barriers to success, our refined intervention will focus not only on acculturation considerations of dietary changes, PA, but also parent stress within the family.

<u>The research questions, objectives and purpose;</u>

The purpose of this study is to refine and optimize an obesity intervention with rural underserved Latino children and their parents that combines a standard family-based behavioral approach, the "gold standard" for pediatric obesity treatment,[16,47,77,78] with a mindfulness approach focusing on stress reduction (now ADAPT+).

Aim 1: Refinement of and optimization of ADAPT+ (ADAPT + mindfulness parent stress reduction combination) manual and intervention.

We assess acceptability of ADAPT and the integration of mindful parenting stress reduction (ADAPT+) to increase healthy lifestyle behaviors consistent with the needs of Latinos living in rural communities. We will conduct a series of focus groups: 1) with our community health facilitators/promotoras. Promotoras are community members who have been acculturated in the US but retain credibility with the target population.[28,29] 2) a series of focus groups with parents

of children (8-12 years old) with obesity to obtain feedback and to refine each of our 6 integrated sessions and evaluate optimization of ADAPT+ sessions.

Aim 2: A small, randomized feasibility and acceptability study (ADAPT+ vs. Enhanced Usual Care comparison/EUC).

Aim 2 will be conducted in two rural communities. This aim evaluates: study sample selection and recruitment, willingness to be randomized and retention; fidelity of intervention administration, intervention adherence, and further refinement of manuals, feasibility of data collection procedures, including collecting a battery of measures from parents and children,* data quality and sensitivity of our measures to our intervention effects over time – from baseline, post-intervention (after 6 sessions), and then 3-months post-intervention. We anticipate that compared to EUC, parent-child dyads in ADAPT+ will have a lower attrition rate and will report greater program satisfaction, and our eating, PA and stress-related measures will be sensitive to the intervention.

The foundation/basis of the proposed study is that parent stress reduction via mindfulness strategies will increase access to mind-body practices that may support and promote implementation of healthy behaviors in both parents and children. This project will provide crucial data to inform a larger trial application to test whether adding mindfulness techniques increases the ability of parents to assist their children in keeping healthy behaviors related to eating and physical activity. This programmatic research advances the understanding of mechanisms of behavioral interventions for improving health and well-being using mind-body practices.

B. *Measures to be used:

Baseline, post-intervention and 3-months follow-up:

Child BMI: Height (to the nearest 1/4 inch) using a stadiometer and weight (to the nearest 1/4 pound) using a medical balance beam scale will be measured by study staff. The CDC Growth Charts will be used to obtain the continuous child BMI z score for gender and age. Our nurse scholar and RNP co-I completes all the anthropometric assessments.

Child Waist-to-Hip Ratio: Circumference of the hip (girth of hips above the gluteal fold) and waist (narrowest part of torso above the umbilicus and below the xiphoid process) will be measured by study staff using an anthropometric measuring tape and used to calculate continuous Waist-to-Hip Ratio. Our nurse scholar and RNP co-I completes all the anthropometric assessments.

Resting Blood pressure for children: assessed in triplicate using an automated blood pressure analyzer, with the participant in a seated position. Elevated BP is defined as either systolic or diastolic BP >90th%ile for age, sex, and height. Our nurse scholar and RNP co-I completes all the anthropometric assessments.

Child Food and Physical Activity Questionnaire: The questionnaire consists of 11 questions on food and physical activity behaviors for youth participants in the study. This was adapted from the USDA Youth Expanded Food and Nutrition Education Program (EFNEP) evaluation tool, the EFNEP 3rd-5th Grade Survey, which was designed and tested by Purdue University Extension Program.

Parent BMI: Height (to the nearest 1/4 inch) using a stadiometer and weight (to the nearest 1/4 pound) using a medical balance beam scale will be measured by the study staff and used to calculate continuous adult BMI score. Our nurse scholar and RNP co-I completes all the anthropometric assessments.

Parent Waist-to-Hip Ratio: Circumference of the hip (girth of hips above the gluteal fold) and waist (narrowest part of torso above the umbilicus and below the xiphoid process) will be measured by the study staff using an anthropometric measuring tape and used to calculate continuous Waist-to-Hip Ratio. Our nurse scholar and RNP co-I completes all the anthropometric assessments.

Resting Blood pressure for Parents: assessed in triplicate using an automated blood pressure analyzer, with the participant in a seated position. Elevated BP is defined as either systolic or diastolic BP >90th%ile for age, sex, and height.

Our nurse scholar and RNP co-I completes all the anthropometric assessments.

Dietary Habits: The Latino Dietary Behaviors Questionnaire: This 13-item self-report survey of dietary habits (in Spanish) assesses 4 areas of eating behavior -- healthy dietary changes; types of drinks consumed, number of meals per day and fat consumption. The LDBQ factor structure is relatively stable over time, and correlates significantly with the 24-HR dietary recall measure and clinical variables such as BMI, and behavioral indicators of diet. It is specifically designed for low literacy populations and has been validated in large samples of ethnically diverse Spanish speaking samples.

Perceived Stress Scale (PSS): Parents complete the 14 item self-report scale that asks participants about their feelings in the past month. The PSS measures psychological stress associated with sex, age, education, income, employment status, and a number of other demographics.

Mindful Eating Questionnaire (MEQ): Parents will complete the Recognize Subscale of the MEQ. The MEQ is a 28-item scale developed to measure the construct of mindful eating, a nonjudgmental awareness of the physical and emotional sensations associated with eating. The Recognize subscale has 9 items and is designed to assess an individual's ability to stop eating when full.

At Baseline Only: Parents will complete the *Stephenson Multigroup Acculturation Scale (SMAS), and a short demographic questionnaire.*

Exit survey: At the end of the intervention, after 6-weeks, parents in both conditions will complete a brief exit survey to assess their overall satisfaction with the intervention and their opinion of its impact on their knowledge of childhood obesity and healthy eating, physical activity behaviors, mindfulness parent stress reduction approaches, as well as how well the content fit their needs and cultural values. For example, what they liked/disliked about the intervention, what additional information they might have wanted, the extent to which they felt they increased their understanding of healthy lifestyle behaviors and stress reduction strategies.

C. Study Design:

1. The study design including information that is needed to answer the research questions;

The study design proposes a refinement and optimization of the original ADAPT obesity intervention protocol to include mindfulness parent stress reduction strategies (ADAPT+),

setting the basis for an efficacy trial of ADAPT+'s efficacy for improving Latino families' eating and PA behaviors.

Targeting two health care disparities by developing a culturally relevant obesity intervention for high-risk Latino youth and their parents (ethnic minorities) living in rural communities (a geographic health disparity). We synthesize behavioral family-based obesity interventions with culture-specific components to promote adaptive health behaviors in a high-risk and underserved population.

Incorporating mindfulness parent stress reduction strategies into a behavioral healthy lifestyle program. Mindfulness-based approaches are shown to decrease stress and contribute to improved eating and PA behaviors, supporting our inclusion of a mindfulness component. This project is the first to incorporate mindfulness to potentially enhance initial and sustained weight loss among Latino youth.

Incorporating bilingual community liaisons from the same community as participants will increase potential for program dissemination, as well as participant engagement. This study will integrate bilingual promotoras from the same community as participants as intervention facilitators.

Individualizing behavior change goals is expected to increase families' commitment to and engagement in working toward their weight-related health goals.

Using a multi-family format, which is consistent with community and collectivist Latino family values. Mutual support within and across child/parent pairs is likely to promote engagement.

Partnering with an established and respected community-based organization, the Hispanic Services Council (HSC). HSC shares a mission consistent with our aims: the reduction of health and education disparities in Latino families. This partnership is expected to increase project buy-in of Latino migrant families and contribute to the dissemination of the program.

2. Sample size;

For Aim 1a: we will conduct a focus group with 6 promotoras (community health workers)

For Aim 1b: we will conduct two focus groups with a total of 20 (max) Latina mothers of 8- to 12-year-old children who are overweight or obese (85th BMI percentile)

For Aim 1c: we will conduct focus groups using one cohort of mothers and their children meeting eligibility to further refine the ADAPT manual. Parents and children will attend all six sessions of ADAPT+ sessions and provide feedback for manual optimization. Latina meal preparers in the family (primarily mothers) and their 8- to 12-year-old children (up to 10 children) will participate.

Summary of Participants 6 community health workers (promotoras or group facilitators); 30 Latina mothers (Aims 1a and b) 10 children (Aim 1c); Total = up to 46 participants (non-clinical trial portions of the project)/

Aim 2: A small pilot RCT will be conducted (clinical trial). There will be cohorts of 8-10 child/parent pairs at each site (2 sites), and 3 intervention cycles. Estimating that all cohorts are the minimum of 8 pairs, we will have a total minimum target sample size of 48 pairs, or 96 total participants (48 parents and 48 youth). If all groups are the maximum of 10 pairs, we will have a maximum total sample size of 60 pairs, or 120 total participants (60 parents and 60 youth). We

aim for a minimum of 48 pairs with a possible range of 48 to 60 pairs based on our study design. Starting in Year 2, in total we will run 3 ADAPT+ and 3 EUC cohorts.

D. Study Population inclusion and exclusion criteria;

C.3.2. Eligibility criteria. Promotoras trained to conduct focus groups by our study site partner, HSC, will identify families living in our target community meeting our eligibility criteria:

1. Latino families with a child between the ages of 8 and 12; Note: pre-adolescents are targeted as this is a developmentally critical age group in terms of developing health-behavior skills and is an age group identified as in need of further study in the Latino population. 2. Child with a BMI %ile of 85 or higher; and 3. The target parent is at least 18 years old, is the main meal preparer, speaks and reads Spanish at a minimum of a 4th grade reading level (able to follow basic instructions in Spanish), and able to perform simple physical exercises. Although both parents and/or other caregivers can participate in the group, only data from the primary parent (main meal preparer) will be used for analyses. The parent is ineligible if he/she is non-ambulatory, is pregnant, or has a medical condition that may be negatively impacted by PA. A child who has a medical/developmental condition that precludes weight loss using conventional diet and PA methods or has been on antibiotics or steroids in the previous three months is also ineligible.

E. The expected results of the research, such as reports, papers, and contributions to theory;

We posit that mindfulness can improve intervention engagement (increasing receptiveness), which are demonstrated critical barriers to Latino families participating in childhood obesity interventions, by simultaneously reducing stress and enhancing the learning process around eating and PA. ADAPT plus mindfulness parent stress reduction to increase healthy eating and PA lifestyle behaviors in both parents and their children.

F. Name of the Principal Investigator and Faculty Advisor if applicable;

Dr. Marilyn Stern

G. Any potential risks to the subjects;

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what the participant would face every day. There are no known additional risks to those who take part in this study.

H. Any experimental procedures or interventions that will be implemented;

The study will assess acceptability of the integration of mindfulness parenting stress reduction into Adaptando Dieta y Acción Para Todos (ADAPT) to increase healthy lifestyle behaviors by: conducting a series of focus groups with our community health facilitators/ promotoras and parents of children (8-12 years old) with obesity to obtain feedback about and refine each of our 6 integrated sessions and evaluate optimization of ADAPT+ sessions.

More specifically, aim 1A) In-depth focus groups with promotoras (3 promotoras from each of our 2 target communities). These groups will be led by Stern and Redwine, and a bilingual

research assistant (RA) to elicit promotoras' impressions and obtain feedback about our proposed 6-session program, ADAPT+. Each proposed component of the program will be reviewed and feedback will be elicited from participants. Aim 1B) Two iterative one-session focus groups of parents (6-10 parents in each group) of children with obesity between the ages of 8 and 12 will be conducted. The ADAPT+ intervention manual will be examined and modified accordingly with each two-hour focus group iteration led by trained promotoras from the same community as participants, along with bilingual RAs to maintain focus group fidelity (e.g., detailed note taking). As they have done in past focus group research promotoras will be trained to elicit feedback via structured interviews and prompts on each of our eight sessions of our combined ADAPT+ intervention manual, including session goals and activities, and their relevance. We are particularly interested in the acceptability (e.g. cultural and individual) of the mindfulness parent stress reduction components, and how best to integrate them into our manualized ADAPT program. In the second group led by promotoras, parents will be asked to provide us with feedback about our refined ADAPT+ manual based on the modifications made after the first parent focus group. Our trained RAs will also use cognitive interviewing strategies to elicit specific feedback from individual parents to help with the further refinement of the ADAPT+ manual. All focus group sessions and interviews will be audiotaped for later coding.

Aim 1C is to further refine ADAPT+ by recruiting a third group of 8-10 primary meal preparers from one of our target communities meeting our eligibility criteria. Children of these parents will also participate in a parallel program at the same time, but separately. For Aim 1C, we will have two of our trained promotoras conduct the revised ADAPT+ 6 sessions intervention in Spanish to parents so that we obtain further information to optimize our ADAPT+ manual.

For Aim 2, the same procedures will be used for recruitment as for Aim 1, but groups of families, or cohorts, during each intervention cycle will be assigned to either ADAPT+ or EUC in line with the following procedures: The ordering of which community site (Plant City or Wimauma) offers ADAPT+ first will be randomly selected for cycle 1, with one community site offering ADAPT+ and the second community site offering EUC. Cycle 2 will counterbalance cycle 1, with the community site that offered EUC in cycle 1 now offering ADAPT+ in cycle 2. ADAPT+ will be randomly assigned to a community site again in cycle 3, with the second community site offering EUC (see Table 3 below). At the baseline session, our bilingual study staff member/RA will answer questions and get parental signed consents and children's verbal assents. The study staff member, along with our co-I Dr. Rodriguez (a certified RNP), will then conduct all anthropometric, stress-related and behavioral assessments.

Table 3. Hypothetical Counterbalance Design

	Dover Clinic	Wimauma Clinic
Cycle 1	ADAPT+ Cohort 1	EUC Cohort 1
Cycle 2	EUC Cohort 2	ADAPT+ Cohort 2
Cycle 3	ADAPT+ Cohort 3	EUC Cohort 3

Summary of the ADAPT+ sessions

Table 2. Session Content of Mindfulness parent stress reduction + ADAPT
***Note: all sessions include Home Practice suggestions**

Session 1: Overview & Get Ready for Success

1. Introductions (8 minutes)
2. Health risks of obesity in Latino families
   a. BMI charts review for parents and children (10 minutes)
   b. Challenges of living in rural area and acculturation (adaptation to culture; foods, etc.) (5 minutes)
3. Effects of Stress on health (10 minutes)
   a. Connection between parents feeling stress and effects on their children (5 minutes)
4. Practicing mindfulness (1 minute)
   a. Mindful stretching/moving (5 minutes)
   b. Short mindful eating exercise (5 minutes)
5. Eating healthy
   a. Reading labels (5 minutes)
   b. Determining portion sizes (2 minutes)
6. Creating SMART goals (8 minutes)
7. Joint Goal Setting and home practice instructions (10)
   a. Goal Setting (Mindful eating home practice)

Session 2: Mindful Meal Prep

1. Homework review and raffle for goal setting (quickly review barriers) (10 minutes)
2. Mindful moment (3 minutes)
3. Reading labels in English (20 minutes)
4. Portion Sizes
   a. Determining portion sizes (2 minutes)
   b. MyPlate. Culturally tailored strategies for portion control (10 minutes).
   c. Limiting portion sizes (10 minutes)
   d. Don't drink your calories (5 minutes)
5. High risk eating situations (10 minutes)
   a. Mindful eating during social large gatherings (1 minute)
   b. Hunger Scale (5 minutes)
   c. S.T.O.P (5-8 minutes)
   d. Body scan (8 minutes)
6. Joint Goal Setting and home practice instructions (10 minutes)
   a. Goal setting (PA and healthy eating Goals, start small and increase over time)
   b. S.T.O.P home practice

Session 3: Parenting in the moment & Increasing Healthy Lifestyles

1. Homework review and raffle for goal setting (5 minutes)
2. Mindful moment (3 minutes)
3. Culturally tailored ways to meal planning
   a. Meal Skipping and Meal Planning.
   b. Eating on a budget.
   c. Breakfast is for the Brain.
   d. Learn to like it.
4. Parenting and role modeling (20 minutes)
   a. Parental styles
   b. What is role-modeling? (10 minutes)
   c. Guild, parenting, and mindfulness
5. Managing stress. Reacting vs responding:
   a. Parents replenish their inner resources.
   b. Mindful communication.
   c. Non-judging.
   d. Seated meditation (Awareness of breath and thoughts; 8 minutes)
6. Joint Goal setting and home practice instructions
   a. Goal setting (PA and healthy eating Goals, parents' role-modeling)
   b. Body scan at bedtime home practice and mindful listening

Session 4: Mindfulness and Making Healthy Behavior Choices + Get Moving!

1. Homework review and raffle for goal setting (5 minutes)
2. Mindful moment (3 minutes)
3. Effects of sedentary lifestyles (10 minutes)
   a. Impact of screen time
4. Being healthy & PA (25 minutes)
   a. Making healthy behavior choices (i.e., mindful walking, dancing, exercising at home)
   b. Scheduling physical activity
   c. Screen-free activities (handout)
   d. Time management and exercise (10 minutes)
   e. Sleep hygiene
5. Dealing with stress using mindfulness and PA (including the family in activities)
   a. Being present and in the moment.
   b. Mindful stretching/moving (8 minues).
6. Joint Goal setting and home practice instructions
   a. Goal setting (PA and healthy eating Goals)
   b. Mindful walking home practice

Session 5: Mindful Eating + Observing vs. Judging

1) Homework review and raffle for goal setting
2) Mindful moment (3 minutes)
3) Food accessibility
4) Making favorite dishes healthier (e.g., tortillas)
   a) Food label activity for usual foods.
   b) Increase intake of fruits and vegetables.
5) Examining & changing hunger cues
   a) S.T.O.P (3 minutes)
      i) Revisit hunger scale if necessary
   b) Mindful eating exercise (observing/letting go of judgements; 8 minutes)
6) Mindfulness, stress and stress reactivity
   a) Implementing mindfulness in daily life. Barriers and facilitators to mindfulness
7) Joint Goal setting and home practice instructions
   a) Goal setting (PA and healthy eating Goals/meal planning, increase fruit/vegetable intake in meal planning)
   b) S.T.O.P home practice during a stress-evoking situation at home

Session 6: Practice not Perfection + Progress & Dealing with Setbacks

1) Homework review and raffle for goal setting
   a) Overcoming barriers (difficulties in meal planning)
2) Mindful moment (3 minutes)
3) Progress discussion
4) **Body scan (8 minutes)**
5) Practical suggestions for continuing progress
   a) Review the healthy recipes book (and maybe potluck).
   b) Coping with setbacks to healthy eating, PA & mindfulness goals in the long-term.

Each session begins with a review of the previous week, monitoring of goal progress, and reviews of weekly family meals. A range of exercises and activities are included in each session. As indicated in Table, several sessions focus on diet and preparing easy, practical meals. Foods discussed include those common within this culture and healthy adaptations, as appropriate. ADAPT+ also includes an emphasis on increasing PA for the whole family. This will be

achieved via guided goal setting and self-monitoring. The mindfulness parent stress reduction approach is based on stress reduction methods by Kabat-Zinn and mindful eating and awareness of family choices. The content includes cultivating mindfulness, such as present-focused awareness, non-judgment of inner experience, nonreactivity to experience, and cultivating compassion, particularly in family lifestyle choices. Sessions include, 1) Mindfulness based stress reduction overview; 2) Mindful Meal Preparation; 3) Parenting in the moment and increasing healthy lifestyles; 4) Mindfulness and making healthy behavior choices; 5) Mindful eating; Observing vs Judging; 6) Practice not perfection.

I. Any potential benefits to subjects;

There is no guarantee of direct benefits by taking part in this research study. This study will increase awareness of how to improve a healthy lifestyle program for Latino families in rural areas and how to work with these families to help them develop a healthy lifestyle.

J. Compensation

For Aim 1c parents will be compensated with a $20 gift card after the first assessment session and a fitness tracker after the last assessment session. Participating children will also receive a fitness tracker and may get some small prizes for their participation throughout the project (e.g., colorful beads).

For Aim 2 parents will be compensated with a $10 gift card after the first session, a $20 gift card for completing the post-intervention exit survey assessment after the 6-weeks of the program, and a $25 gift card for completing the 3-months follow-up measures.

Human subjects considerations including description of the informed consent process; if applicable include a discussion of safeguards that are in place to protect potentially vulnerable subjects such as children, prisoners, the cognitively impaired, institutionalized or critically/terminally ill; discussion of how the privacy and confidentiality of the subjects will be maintained

Consent and assent will be obtained by a bilingual research assistant. Consent forms will be available in both English and Spanish. Parents may choose their preference. Consent forms will be written in at a fourth-grade level. Reading at this level has been made part of the inclusion criteria. Parents will also be briefed on the study before signing consent forms and are free to ask questions. Children will get all the information explained using a children friendly language and verbal assent will be requested.

Due to Covid-19 consent process for Aim 1B will be slightly different than originally planned. For this Aim, our promotoras (community health workers) will be running small focus groups in person, with appropriate precautions, social distancing, and masks, as previously approved. However, it is likely that our bilingual research assistants (RA) will only participate via videoconferencing, following USF safety standards. For this reason, informed consent from these mothers will be acquired via videoconferencing. Mothers will have written copies of the consent forms (approved in 5/23/2019) and our RA will go over the consent via videoconferencing and then have each mother sign the consent form prior to beginning the focus group with the promotoras. These consent forms will then be collected and mailed back to USF in a secure envelope to be stored in our locked file cabinet. We will provide the Hispanic Services Council director with these envelopes and gift cards for participants prior to the focus groups being

scheduled. The RA will then continue to monitor the focus groups, as originally planned, via videoconferencing.

To protect confidentiality, personal information will be restricted to the research team, government or university individuals who need to know about the study, and the USF Institutional Review Board. Any information that is published will not contain names or other identifiable information. Data will be restricted to the research team and any physical records will be locked away. Participants will not be provided any identifiable information about individuals other than themselves. Lastly, we will not receive or disclose any protected health information.

K. Statistical Analysis Plan

Preliminary evaluation of participants' response to the interventions will be examined using quantitative data. While evaluation of outcomes is more appropriate for a fully-powered R01, we will examine variance and effect sizes of key outcomes from pre- to post-intervention, as well as post-intervention to 3-month follow-up using non-parametric tests and confidence intervals. The randomized trial is powered to detect an average estimated effect size equivalent to Cohen's d of 0.50 with the minimum sample size of 96 participants (i.e., 48 children, 48 parents). Analyses will explore potential patterns related to attrition. Every effort will be made to collect follow-up data from all participants, regardless of whether they completed the intervention.

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