IRB Study Number: 20160415
Version 14.0, Date: 10/26/2021

1) Protocol Title

St. George K01: Family-based eHealth Obesity Prevention Intervention for Hispanic Adolescents

2) IRB Review History*

This study was approved on 6/14/2016.

3) Objectives*

Because Hispanic adults and adolescents are most likely to access the internet from smartphones, an innovative way to package family-based interventions for Hispanic families may be through the use of web and mobile phone technology (eHealth). Previous eHealth interventions for improving adolescent physical activity, sedentary behavior, and diet show promise; however, these approaches have largely targeted individual adolescents only (e.g., through computer/ video games) with limited parental involvement. Integrating family-related constructs, such as family functioning, more directly within eHealth interventions, particularly those targeting Hispanics, may thus improve their efficacy and effectiveness. As such, the specific aims of this study are:

AIM 1: To conduct formative research which will inform the development of a family-based eHealth obesity prevention intervention for increasing moderate-to-vigorous physical activity, decreasing sedentary behavior, and improving quality dietary intake in Hispanic adolescents.

To accomplish this aim, we will employ a user-centered design approach to integrate the perspectives of Hispanic parent-adolescent dyads during the intervention development process. Specifically, we will: **1a)** conduct four focus groups and/or individual interviews with 20 Hispanic parents and adolescents to assess the needs and capabilities of the target audience; **1b)** develop visual mockups of the intervention known as "paper prototypes" and iteratively revise and retest them through collecting usability and user feedback data from three groups of 5 Hispanic parent-adolescent dyads; **1c)** develop a fully functional intervention prototype; and **1d)** conduct a field trial with 10 Hispanic parent-adolescent dyads using the fully functional eHealth intervention prototype to refine intervention content and usability accordingly.

AIM 2: To conduct a pilot randomized trial to determine the feasibility, acceptability, and preliminary effects of a family-based eHealth obesity prevention intervention for increasing moderate-to-vigorous physical activity, decreasing sedentary behavior, and improving quality dietary intake in Hispanic adolescents.

To accomplish this aim, we will: **2a)** recruit 50 parent-adolescent dyads; and **2b)** randomize dyads to a family-based eHealth intervention or digital standard of care. It is hypothesized that the experimental intervention will be feasible, acceptable, and show promising effects vs. digital standard of care in increasing moderate-to-vigorous physical activity, decreasing sedentary behavior, and improving quality dietary intake in adolescents at post intervention and a 6 month follow-up. Changes in parent physical activity, sedentary behavior, and diet will be assessed as secondary outcomes and changes in family functioning will be examined as a potential mediator of the effect of condition on outcomes.

4) **Background***

Obesity is the most prevalent risk factor for cardiovascular disease (CVD) among adolescents, with 34.5% of 12-19 year olds currently overweight or obese. These rates are disproportionately higher in ethnic minority adolescents, including Hispanics, 38% of whom are overweight or obese compared to 31% of non-Hispanic Whites. Although engaging in physical activity and healthy dietary behaviors in adolescence reduces CVD risk, only 26% of Hispanic adolescents are physically active for 60 minutes/day and nearly 40% watch ≥3 hours/day of television. The diets of Hispanic adolescents have also been shown to contain high levels of fat and added sugar, and low levels of fruits and vegetables. Effective preventive interventions are thus urgently needed to promote healthy lifestyle behaviors in this population.

Ecological models of pediatric obesity consistently underscore the important role of the family system, which may serve to offset risks in other domains. In fact, meta-analyses of pediatric obesity interventions often conclude that family-based programs, or those that involve parents, are among the most efficacious. Family-based interventions may be especially relevant for Hispanics due to *familismo*, or a strong commitment to the family system. Despite the relevance of the family for Hispanics, however, there is surprisingly little research examining the effects of family-based obesity prevention programs in Hispanic adolescents.

An innovative way to package family-based obesity prevention interventions for Hispanic families may be through the use of web and mobile phone technology. Technology use has become pervasive, with data from nationally representative surveys indicating 84% of adults and 95% of adolescents access the internet. Surprisingly, Hispanics (76%) are more likely than non-Hispanic White internet users (60%) to access the internet from a mobile device. The use of eHealth interventions thus presents a highly promising and viable option for delivering family-based obesity prevention interventions to Hispanic parents and adolescents.

Systematic reviews of eHealth interventions for adolescent physical activity, sedentary behavior, and dietary change published in the last five years suggest they are feasible, acceptable, and demonstrate some improvements in healthy lifestyle behaviors. These interventions, however, have been largely targeted towards individual adolescents (e.g., through computer/video games) with limited or no parental involvement, which may account for their generally small and/or lack of sustained effects. When parental involvement has been integrated, it has generally included health education only (e.g., healthy recipes). One exception is a recent web-based intervention for mother-daughter dyads living in public housing which targeted improvements in family communication and demonstrated significant improvements in girls' fruit intake and mothers' physical activity and vegetable intake. To date, only two other adolescent obesity-related interventions have targeted improvements in family processes such as positive parenting using an eHealth approach; both of these, however, were treatment (not *prevention)* studies for African American adolescents. Integrating family functioning more directly within eHealth interventions, particularly those targeting Hispanics, may enhance their efficacy and effectiveness, but more research is needed.

In summary, given the dearth of research on family-based approaches for obesity prevention in Hispanic adolescents, this study will provide novel and significant information regarding the development and preliminary effects of a family-based eHealth obesity prevention intervention that integrates web and mobile phone technology.

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5) Inclusion and Exclusion Criteria*

This project has two research aims and will be conducted across four phases. Aim 1 employs a user-centered design approach to elicit feedback from members of the target population throughout the intervention development process across three phases: focus groups and/or individual interviews, testing of paper prototypes, and a field trial. Aim 2 (the fourth and final phase) is a pilot randomized trial of a family-based eHealth obesity prevention intervention. All inclusion and exclusion criteria listed below (with the exception of exclusion criteria "e," applied to Aim 2 participants only), will apply to all study participants:

Inclusion criteria:

(a) Female and male adolescents whose primary caregiver self-identifies as Hispanic
(b) Adolescent is between the ages of 12-15;
(c) Adolescent lives with an adult primary caregiver willing to participate;
(d) Both parent and adolescent own a smartphone with internet access;
(e) Adolescent does not meet recommendations for fruit and vegetable intake (proxy for overall diet quality) as determined by a validated two-item screener;
(f) Adolescent does not meet physical activity guidelines as determined by responses on a validated two-item screener AND self-reports engaging in >2 hours/day of screen time (proxy for overall sedentary behavior) using three items.

Exclusion criteria:

(a) Adolescent's body mass index for age and gender is ≥ 95th percentile ("obese" range);
(b) Adolescent has a chronic medical condition (e.g., type 2 diabetes) that requires intensive lifestyle modification;
(c) Adolescent has a diagnosed developmental delay that would interfere with understanding program materials;
(d) Parent or adolescent has a diagnosed medical or psychiatric condition and is currently taking medications that would interfere with changes to physical activity or diet (e.g., adolescent is diagnosed with Attention Deficit Hyperactivity Disorder and is currently on stimulant medication);
(e) Family is planning to move out of the South Florida during the study follow-up period

6) Number of Subjects*

A total of 95 Hispanic adolescent-primary caregiver dyads ("families") will participate throughout the duration of the study, conducted across four total phases. The breakdown of participants by research aim and study phase is detailed below:

- Aim 1, Phase 1: Focus groups and/or individual interviews (n = 20 families)
- Aim 1, Phase 2: Testing of paper prototypes (n = 15 families)
- Aim 1, Phase 3: Field trial (n = 10 families)
- Aim 2: Pilot randomized trial (n = 50 families)

7) Study-Wide Recruitment Methods*

Participants will be recruited from local pediatric primary care clinics in South Florida, including the following: UHealth Pediatrics at the Professional Arts Center, University of Miami Pediatric Mobile Clinic, UHealth at

Kendall, Ambulatory Care Center West Pediatrics at Jackson Memorial Hospital, Kidstown Pediatrics, South Florida Pediatric Partners, Borinquen Medical Centers, Primecare Family Centers, ECC Pediatrics, Dr. Ileana Fuentes Clinic, Castro Pediatrics, Gables Pediatrics, Belkys Bravo Pediatrics, Pediatrics & Family Medicine Associates, Dr. Rene Lopez-Guerrero Clinic, Dr. DeChurch Clinic, and Francisco E. Martinez Clinic.

Hispanic families who participated in previous University of Miami studies AND agreed to be contacted for future studies will additionally be invited to participate in the current study. Only staff members approved on both study protocols will contact these participants by phone to invite them to learn more about the current study. In the case of previous University of Miami studies already closed on eProst (to which we cannot add our staff members), we will list their eProst protocol numbers here: 20180944.

We will also obtain a list of potentially eligible participants from the UM Consent to Contact Database. The following criteria (or similar) will be used to generate the patient contact list: Healthy volunteers, Hispanic, Parent of a young teen (12-15 years of age). After receiving the lists of potentially eligible participants, study staff will contact individuals via phone using the Consent to Contact Script.

We will additionally recruit families through word-of-mouth, referrals from families who participated in previous phases of the study, and through posting ads on social media (e.g., Facebook, Instagram) and flyers **(See "Healthy Juntos Flyer")** in various locations throughout the community **(See "Media Tool Kit: Brochure, Flyer and Palm card")**. For those who learn of the study via social media, they will first be asked to provide their electronic consent to a brief online eligibility pre-screener (**See "Online Eligibility Pre-Screener"**). Once consent has been provided, individuals will be directed to the pre-screener in the project's landing page, the responses to which will be captured in REDCap. Study staff will review all completed online pre-screeners and determine whether respondents appear to meet preliminary eligibility criteria. Study staff will call the respondents who meet the preliminary criteria to complete the screening process. Participating families will be encouraged to have interested friends contact the study team and will be compensated $10 for every referral of a potentially eligible family received.

Recruitment will occur over a four year period and will include multiple waves corresponding to each of four phases of the study: focus groups and/or individual interviews (n=20), testing of paper prototypes (n=15), field trial (n=10), and pilot randomized trial (n=50).

To recruit families from the pediatric primary care clinics, a point person from each clinic will work with study staff members to identify Hispanic adolescents (and their caregivers) scheduled for a doctor's visit. The clinic staff will inform study staff at least one day in advance whether a Hispanic adolescent between the ages of 12 and 15 is scheduled to visit the clinic. During the family's medical appointment, providers will ask the family whether they are interested in learning more about a study to improve healthy lifestyle behaviors, including physical activity and nutrition among Hispanic adolescents. If the family is interested, they will be instructed to contact the study team or provide their verbal consent to be contacted by the study team for screening.

Families who meet the inclusion/exclusion criteria and are interested in participating will be given a detailed description of the study by study staff members. Prior to data collection, participants will complete an informed assent form (adolescents) and an informed consent form (caregivers) either in-person or remotely. To avoid coercion of the adolescent by the parent, we will ask parents give the adolescent privacy. In case the

adolescent does not want to sign, the family will be told they did not meet one or more of the inclusion/exclusion criteria but the study staff member will not reveal to the parent that the adolescent did not want to participate (to avoid any consequences to the adolescent).

Participants will be compensated as follows during each of the study phases:

Study Phase	Parent Compensation	Adolescent Compensation
Aim 1, Phase 1: Focus groups and/or individual interviews	$50	Two movie tickets
Aim 1, Phase 2: Testing of paper prototype	$60	Three movie tickets
Aim 1, Phase 3: Field trial	Weekly $5 digital gift card contingent on both parent and adolescent completion of weekly survey $40 digital gift card for final interview Keep their wrist-worn activity tracker	$30 digital gift card for final interview Keep their wrist-worn activity tracker
Aim 2: Pilot randomized trial	Digital gift cards in the following amounts: T1 = $60; T2 = $65 $40 digital gift card for final interview Keep their wrist-worn activity tracker	Digital gift cards in the following amounts: T1 = $20; T2 = $20 $30 digital gift card for final interview Keep their wrist-worn activity tracker

8) **Study Timelines***

The duration of each family's participation in the study is contingent on the study phase to which they are recruited to participate. Details are below:

- Aim 1, Phase 1: Focus groups and/or individual interviews (n = 20 families will be recruited to participate in a single 1-2 hour session)
- Aim 1, Phase 2: Testing of paper prototypes (n = 15 families will be recruited to participate in a single 1-2 hour session)
- Aim 1, Phase 3: Field trial (n = 10 families will be recruited to participate in an 8-week eHealth intervention program. In addition to completing eight weekly eHealth sessions (each lasting 45 minutes) from their own smartphones or computers, families will complete brief weekly electronic surveys to provide their feedback on the eHealth intervention)
- Aim 2: Pilot randomized trial (n = 50 families will be recruited to participate in measures at two time points: baseline, and 2-months post baseline. Each measurement session is anticipated to last two and a half hours. Families randomized to the eHealth intervention condition will

additionally complete eight weekly eHealth sessions (each lasting 45 minutes) from their own smartphones or computers.

The overall study (including all four phases described above) will be completed by October 2022.

9) Study Endpoints*

- Aim 1, Phase 1- Aim 1, Phase 3: Qualitative feedback from participants at different stages in the intervention development process to inform ongoing intervention design
- Aim 2, Phase 4:
  - *Primary:* Changes in adolescent moderate-to-vigorous physical activity, sedentary behavior, and quality dietary intake
  - *Secondary*: Changes in parent moderate-to-vigorous physical activity, sedentary behavior, and quality dietary intake; family functioning examined as a potential mediator of the effect of condition on outcomes

10) Procedures Involved*

Aim 1 of this study employs a user-centered design approach to elicit feedback from members of the target population at various stages throughout the intervention development process. We will work with technologists from a technology research center to create visual mockups, known as "paper prototypes," and a fully functional intervention prototype. We will employ a user-centered design approach, or an iterative process whereby an understanding of the needs and preferences of end users is obtained to inform intervention content and usability. The user-centered design process in this study will include focus groups and/or individual interviews, development and testing of initial paper prototypes to create a fully functional prototype, and a field trial for testing the fully functional prototype. Procedures for each of these phases of the user-centered design approach are detailed below:

Aim 1, Phase 1: Focus Groups and/or individual interviews. We will first conduct four focus groups (2 parent-only and 2 adolescent-only groups; 10 individuals/group) and/or a series of individual interviews to inform intervention content and technical development. Prior to focus group and/or individual interview sessions, participants will complete brief questionnaires including demographic items and items about their technology use. Participants will also have their height and weight measured by study staff (or by a medical provider at their primary care clinic). Height will be measured using a stadiometer. Weight will be measured using a digital scale.

During focus group and/or individual interview sessions, parents and adolescents will be asked a series of questions designed to understand how they currently use technology for their health, how they define a healthy lifestyle, how they participate in healthy lifestyle activities with their families, and what they think of the research team's ideas to develop an eHealth intervention ***(see "Focus Group/Interview Question Guide")***. Focus groups and/or individual interviews will be guided by previously established methods for conducting focus groups and/or individual interviews with Hispanics (e.g., bilingual facilitator), will be conducted at either the researchers' office, an office in one of the primary care clinics, the participants' home, by phone, or by videoconference, will last 1-2 hours, and will be audio-recorded and then transcribed by study team members or the National Captioning

Institute, a professional transcription agency. Results will be used to create visual mockups, or "paper prototypes" of the eHealth intervention.

Aim 1, Phase 2: Testing of Paper Prototypes: We will then iteratively collect usability and user feedback data from parent-adolescent dyads. Prior to formal consenting/assenting procedures, parents and adolescents will provide verbal consent to have the adolescents' height and weight measured by study staff to confirm their eligibility for this phase of the study. Height will be measured using a stadiometer. Weight will be measured using a digital scale. Once participants formally consent for the study, parents will also have their height and weight measured and recorded. Parents and adolescents (separately) will then be shown paper and minimally-functioning versions of the intervention and asked to interact with them by pointing to features/links they might select. As they interact with the prototypes, they will be presented with the next "screen" and asked to "think aloud" as they make their selections ***(see "Paper Prototype Interview Guide")***. The "think aloud" method is used to understand participants' navigation of websites, identify problems early in the design process, and develop suggestions for improvement. They will additionally be asked general questions related to what they liked most/least about the prototypes, how they might be improved, and how likely they would be to use a website that looked like the prototypes. Finally, participants will complete a brief demographic survey and a measure of the prototype's usefulness and ease of use ***(see "USE Questionnaire")***. The entire session will be conducted at either the researchers' office, an office in one of the primary care clinics, the participants' home, or a location of the participants' choosing that offers privacy (e.g., a private room at the participants' local library) will last 1-2 hours and will be audio-recorded and transcribed by study team members or the National Captioning Institute. Potential flaws to the eHealth intervention will be identified and corrected as participants provide feedback. Data gathered during paper prototype testing will then be used to create a fully functional intervention prototype.

Aim 1, Phase 3 Field trial: During the final phase of formative testing, we will conduct a field trial using the fully functional eHealth intervention prototype. Field trials involve the collection of data in users' natural environments and can evaluate technology for flaws that will only emerge through use over time. Participants will be instructed to wear a physical activity monitor and interact with the intervention using their own smartphones and/or computers over the course of eight weeks.

Prior to formal consenting/assenting procedures, parents and adolescents will provide their height and weight. Following the informed consent/assent process, participants will be asked to complete a brief demographic survey. Study team members will then provide an overview of smartphone security education to each participant ***(see "Smartphone Security Tips Checklist")***, show participants how to log in to and use the program, and review the intervention terms of service and privacy policy following log-in.

At the end of each week, participants will be asked to complete a brief electronic survey that asks them to rate weekly content, including what they liked/disliked and would change about each session ***(see "Field Trial Weekly Questions")***. At the end of the eight weeks, participants will be asked to complete a brief survey and a final interview to discuss their overall experience using the entire program ***(see "USE questionnaire and "Field Trial Final Interview Question Guide")***. The final interview session will be conducted by phone or videoconference, will last 1–2 hours, and will be video or audio-recorded and

then transcribed by study team members or the National Captioning Institute. Refinements will be made to the eHealth intervention prior to the pilot study.

Aim 2 is a pilot randomized trial of the family-based eHealth obesity prevention intervention. The pilot study will use a mixed design with two levels of intervention (family-based eHealth intervention and digital standard of care comparison) as the between subjects factor and two repeated measures (T1=baseline, T2=post-intervention) as the within-subjects factor. To confirm adolescent's eligibility for this phase of the study, parents and adolescents will provide verbal consent to have the adolescents' height and weight measured by study staff. Once participants formally consent for the study, parents will also have their height and weight measured and recorded. During each time point, the following measures will be collected from both parents and adolescents. Participants will complete questionnaires using their own smartphones or desktop computers.

Body Measures: Height will be measured using a stadiometer. Weight will be measured using a digital scale or a bioimpedance scale. Waist circumference will be measured using a tape measure. Body composition will be obtained with a bioimpedance scale. Each measurement will be taken at least twice.

Lifestyle Behaviors (for eHealth intervention condition ONLY): Daily steps and dietary intake will be measured using a wrist-worn device. Participants will wear the monitor all day and night for the first two months, only removing it to shower and do other activities, such as swimming, where the monitor would be underwater. Participants may receive phone calls to check on compliance with wearing the monitor ***(see "Instructions for Physical Activity Monitor")***.

Questionnaires: Parents and adolescents will complete self-reported questionnaires that assess constructs including demographics, physical activity, dietary intake, parenting practices, family relations, parent-adolescent communication, acculturation, and motivation ***(see "Parent Measures Packet" and "Adolescent Measures Packet")***.

Once families complete the baseline assessment, they will be randomized (1:1) into one of two possible study groups, eHealth Intervention or digital standard of care. Participants will be informed of their group assignment by phone.

eHealth Intervention Group: Participating parents and adolescents will receive a wrist-worn physical activity tracker (Fitbit). Study team members will provide an overview of smartphone security education to each participant ***(see "Smartphone Security Tips Checklist")***, show participants how to log in to and use the program, and review the intervention terms of service and privacy policy following log-in.

Families randomized to the eHealth intervention will be log in to a secured website for approximately 45 minutes each week for a total of eight weeks. The eHealth intervention will be delivered primarily through smartphones but will be developed using a responsive web design, or one that "responds" to the users' device (e.g., smartphone, computer) by automatically adjusting the viewing experience (e.g., image resolution, size). This design will provide participants with flexibility in engaging with intervention content.
The website will include didactic content on healthy lifestyle behaviors (for parents/adolescents), a family behavior change tool for setting weekly goals (for parents/adolescents), and a positive parenting tool (for

parents only), all of which will be developed in accordance with participant feedback from the formative development stage of the study (Aim 1). A HIPAA-compliant secure server architecture will be developed in support of the program described above. This will consist of an industry-standard Ubuntu Linux server using Ruby on Rails application software.

In addition, and to increase participant compliance/reduce attrition often observed in eHealth interventions, human support ("supportive accountability") will be provided weekly. Each family will be assigned a "coach" who will use video conferencing software or phone to engage in a 15-30 minute conversation regarding their family's progress. Sessions may be recorded for the purposes of training and supervision. No recording will be done without participant's prior knowledge and consent.

At the end of each week, participants will be asked to complete a brief electronic survey that asks them to rate weekly content, including what they liked/disliked and would change about each session ***(see "Pilot Study Weekly Questions")***. At the end of the eight weeks, participants will be asked to complete a brief electronic survey ***(see "USE questionnaire").*** In addition, a randomly-selected subset of participants (n=12-15) assigned to the intervention condition will be asked to complete a final interview to discuss their overall experience using the entire program ***(see "Pilot Study Final Interview Question Guide")***. The final interview session will be conducted by phone or videoconference, will last 1–2 hours, and will be video or audio-recorded and then transcribed by study team members or the National Captioning Institute.

Digital Standard of Care Group: Families randomized to digital standard of care will receive a list of free health apps and publicly available health websites *(**see "Digital Health Resource List")***. Study team will contact them when it is time for the scheduled measures. In addition to the standard measures, participants will be asked to complete a brief electronic survey about their experience using the listed apps and websites at 2 months and 8 months post baseline *(**see "Digital Standard of Care Survey")***.

11) Data and Specimen Banking*

NA – no specimens will be collected.

12) Data Management*

Aim 1 of this study employs a user-centered design approach to elicit feedback from members of the target population at various stages throughout the intervention development process. All qualitative data gathered throughout this process (focus groups and/or individual interviews, testing of paper prototypes, field trial) will be transcribed by study team members or the National Captioning Institute. Once transcripts are completed, data will be analyzed using a rapid assessment and/or general inductive approach to derive themes. A general inductive approach is a systematic procedure that entails multiple readings and interpretations of transcripts reflective of participant responses. Although findings are influenced by the evaluation objectives, findings will be derived directly from the raw data (i.e., participants' comments). Study staff members will read all transcripts in detail and will iteratively develop a comprehensive code book outlining all category labels and descriptions. The code book, along with predefined decision rules, will guide the process of coding. A qualitative software program will be used to perform a content analysis.

Descriptive statistics (e.g., means, standard deviations) will be used to summarize quantitative data gathered from the USE Questionnaire during this phase.

Aim 2 is a pilot randomized trial of the family-based eHealth obesity prevention intervention. Because this is a pilot study, sample size was not determined through traditional power analyses but by using the guide of 15 to 30 participants per condition. Given the small sample size (n = 50), we will first examine descriptive statistics over time by condition. Trajectories of outcomes by condition will be plotted to visualize potential intervention effects (i.e., differences in trajectories by condition). Percentages of outcome changes by condition from baseline to 8 weeks follow-up will also be calculated to show intervention effects. To test the hypothesis that the intervention will show promising effects compared to digital standard of care in increasing moderate-to-vigorous physical activity, reducing sedentary behavior, and improving quality dietary intake in adolescents at post intervention, we will run latent growth models for each of the three primary outcomes of interest. Power for latent growth models is often much greater than that of repeated ANOVA methods because the unit of analysis is the slope of the trajectory, and I have two time points. In estimating these models, we will focus on effect size estimates as opposed to statistical significance. Latent growth modeling analyses will test differences in trajectories of outcomes over the two time points across the two conditions. Effect sizes will be calculated as the ratio of the difference in the slope between conditions divided by the standard deviation of the slope growth factor. After conducting the latent growth analysis, the model-estimated outcomes will also be plotted (by condition) to visualize trajectories over time by condition. This same procedure will be used to examine secondary parent outcomes. Finally, exploratory mediation analyses will be conducted using the "product of coefficients" test to examine whether the effects of condition on the outcomes will be partially mediated by changes in family functioning.

13) **Provisions to Monitor the Data to Ensure the Safety of Subjects***

We do not expect for this study to create more than minimal risk for participating families; however, the study will be monitored for safety by the study investigators.

14) **Withdrawal of Subjects***

Families will be informed that their participation in the study is completely voluntary and that they have the right to withdraw at any time without any negative consequences.

Circumstances under which participants will be withdrawn from the study include: the parent or adolescent is arrested, reports suicidal ideation, or experiences some other extreme adverse event. If a participant is arrested, reports suicidal ideation, or some other extreme adverse event, a qualified study staff member (i.e., Dr. Sara St. George, a licensed psychologist) may ask them to withdraw from the study, and if appropriate, refer them to necessary services. According to IRB, if a participant becomes incarcerated while enrolled in a study, all research interactions and interventions with that participant, and the obtaining of identifiable private information about the participant must cease.

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15) **Risks to Subjects***

Potential risks to participants are described below by study aim:

Aim 1 of this study employs a user-centered design approach to elicit feedback from members of the target population at various stages throughout the intervention development process.

- **Participation in qualitative data collection (through focus groups and interviews):** There is the potential for participants to be bothered by the questions asked during focus groups or individual interviews, which may make them feel uncomfortable, angry, sad, or embarrassed. Participants might also feel fatigued after focus group or individual interview sessions.
- **Body Measures (for Aim 1, Phases 1 and 2 ONLY):** Participants will have their height and weight measured. Some concerns have been raised regarding potential adverse effects of anthropometric measurements used to assess body composition and categorize weight status. However, in 2010, the U.S. Preventive Services Task Force (USPSTF) reiterated their earlier statement (2005) that no direct evidence supports potential harms such as poorer self-concept, eating disorder pathology, or mental health problems, and that these were not incurred by standard obesity screening procedures used with children and adolescents (USPSTF, 2010; Whitlock et al., 2005). There is the potential risk of embarrassment for girls undergoing anthropomorphic assessments; however, *care will be taken to conduct this examination in private and to minimize discomfort*.
- **Questionnaires:** Participants will complete self-reported questionnaires. No side effects have been noted in the current literature in association with the self-reported assessments used in this study, although, as with many assessment batteries, some people may experience mild fatigue or momentary concern about their ability to perform well. Some participants may also feel embarrassed and/or bothered by some of the questions asked.

Aim 2 is a pilot randomized trial of the family-based eHealth obesity prevention intervention.

- **Randomization to the eHealth intervention condition:** There may be some discomfort from increasing physical activity levels or changing eating behaviors as a result of participation in the eHealth intervention condition. The possibilities include, but are not limited to some muscle and joint stiffness. This stiffness generally subsides in 1 or 2 days, and is not considered to be serious.
- **Body Measures:** Participants will have their height, weight, waist circumference, and body composition measured. See potential risks for body measures listed under Aim 1 above.
- **Lifestyle Behaviors Measures:** Participants will wear physical activity bands to monitor their physical activity levels. There is no known risk of injury associated with wearing the activity bands in this study. The bands are worn around the wrist like many commercially available bands, are small and unobtrusive, and should cause no discomfort. Participants will be monitored to determine if they are experiencing discomfort due to wearing the devices.
- **Questionnaires:** See potential risks for questionnaires listed under Aim 1 above.

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16) **Potential Benefits to Subjects***

There is no direct tangible benefit, other than the monetary incentive for participants involved in the focus groups and/or individual interviews and testing of paper prototypes. The most important benefit from participation in the field trial and pilot study is that adolescents may reduce their risk for obesity and both adolescents and parents may improve their physical activity, sedentary behavior, and diet. Additionally, families may benefit through improvements in communication and family functioning.

17) **Vulnerable Populations***

The research involves youth under the age of 18. To avoid coercion or undue influence, adolescents will assent and complete study measures separately from their primary care giver(s). In case the adolescent refuses to assent, the family will be told they did not meet one or more of the inclusion/exclusion criteria; to avoid any consequences to the adolescent, study staff will not reveal to the parent that the adolescent did not assent.

18) **Multi-Site Research***

NA – this study is not a multi-site study

19) **Community-Based Participatory Research***

NA – this study is not considered community-based participatory research

20) **Sharing of Results with Subjects***

NA – results of this study will not be shared with participants

21) **Setting**

The research team will identify and recruit potential participants from two pediatric primary care clinics affiliated with the University of Miami Health System, Jackson Memorial Hospital, and a private pediatric primary care clinic in the community. The first is a mobile clinic that travels to underserved areas in South Florida to provide free medical care to underinsured, predominantly ethnic minority youth. The second clinic is located within Jackson Memorial Hospital, South Florida's only public health hospital, and serves mostly ethnic minority youth. The third clinic is located on the University of Miami Miller School of Medicine campus. The fourth is a private practice in the community. All recruitment and consent/assent activities as well as data collection will occur either in-person or remotely (by phone or videoconference).

For Aim 2, all data collection at T1, T2, and T3 will occur at either the researchers' office, an office in one of the primary care clinics, the participants' home, or a location of the participants' choosing that offers privacy (e.g., a private room at the participants' local library). The intervention will be delivered online; thus, participants will most likely be in their homes or places with Internet access (e.g., school, library) to receive the intervention.

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22) **Resources Available**

Investigative Team:

- **Dr. Guillermo Prado** is Miller Professor of Public Health Sciences, Director of the Division of Prevention Science and Community Health in the Department of Public Health Sciences at the University of Miami Miller School of Medicine, and Dean of the Graduate School at the University of Miami. Dr. Prado, a trained epidemiologist, has been conducting research with Hispanic families for 15 years and has substantial experience coordinating and managing the research activities of major longitudinal randomized clinical trials including recruitment, data collection, quality control, data analysis, and dissemination of study findings. Throughout his career, Prado has received over $75 million dollars of extramural funding as either PI, Co-I, or mentor and has published over 100 peer-reviewed papers. He co-developed *Familias Unidas*, a Hispanic-specific family-based preventive intervention found to be efficacious and effective in preventing and reducing substance use and sexual risk behaviors across four NIH-funded R01 randomized controlled trials. Related to the current study, Dr. Prado's most recently funded R01 trial is examining the efficacy of an adapted version of *Familias Unidas* for increasing physical activity and healthy dietary intake in Hispanic adolescents.

- **Dr. Sara M. St. George** is an Assistant Professor in the Division of Prevention Science and Community Health in the Department of Public Health Sciences at the University of Miami Miller School of Medicine. She has begun to establish herself as a pediatric obesity prevention scientist. Her research focuses on developing and evaluating theoretically-based interventions for ethnic minority adolescents which integrate multiple influential social systems (e.g., family, peers) to improve adolescent physical activity, sedentary behavior, and dietary intake patterns. She has developed the beginnings of an independent program of research in pediatric obesity prevention funded by a diversity supplement, pre-doctoral fellowship, and research award from the American Psychological Association's Division 38 (Health Psychology). She has held leadership roles, such as Intervention Coordinator, on four randomized controlled efficacy trials aimed at promoting positive health behaviors in ethnic minority adolescents and adults using family-, school-, and community-based approaches. She has also been actively involved in the dissemination of important research findings and has contributed to 26 peer-reviewed publications, 3 book chapters or encyclopedia entries, and over 50 conference presentations. Dr. St. George will be responsible for managing all aspects of the present study with supervision from Dr. Prado.

- Other study staff, including assessors, research assistants, and students, will be trained in study operating procedures, including screening potential study participants, consent/assent, and conducting assessments. Study staff members will be responsible for scheduling assessments and for maintaining cordial contact with participants between assessment time points to maximize retention rates at assessments. All study staff members will be CITI trained and adequately informed about the protocol, research procedures, and their duties and functions. Trainings will be held to ensure all study staff members are adherent to the study procedures. Regular meetings will also be held to discuss study updates, issues or concerns.

Other Resources:

Participants will be recruited from the following pediatric primary care clinics: UHealth Pediatrics at the Professional Arts Center, University of Miami Pediatric Mobile Clinic, UHealth at Kendall, Ambulatory Care Center West Pediatrics at Jackson Memorial Hospital, Kidstown Pediatrics, South Florida Pediatric Partners,

Borinquen Medical Centers, Primecare Family Centers, ECC Pediatrics, Dr. Ileana Fuentes Clinic, Castro Pediatrics, Gables Pediatrics, Belkys Bravo Pediatrics, Pediatrics & Family Medicine Associates, Dr. Rene Lopez-Guerrero Clinic, Dr. DeChurch Clinic, and Francisco E. Martinez Clinic.

- **UHealth Pediatrics at the Professional Arts Center.** The Department of Pediatrics at UHealth is nationally and internationally acclaimed for education, research, patient care, and biomedical innovation. Offering a variety of services from routine healthcare and immunizations to the treatment of severe and chronic illnesses, UHealth Pediatrics is integrated into a dynamic research environment where innovative and effective preventive and treatments services are delivered and under development. UHealth Pediatrics is affiliated with Holtz Children's Hospital, one of the largest children's hospitals in the southeast United States. With over 150 child health specialists honored as Best Doctors®, UHealth Pediatrics has more Best Doctors than any institution in South Florida. UHealth Pediatrics at the Professional Arts Center is one of 9 UHealth sites. The pediatrics offices at UHealth have 10 exam rooms, a small conference/meeting area, and a reception/waiting area. UHealth Pediatrics at the Professional Arts Center is directed by Dr. Lourdes Forster.
- **The University of Miami Pediatric Mobile Clinic**. This clinic has provided medical care to uninsured children since 1992. Services provided include well-visits, sports physicals, immunizations, management of chronic conditions, urgent care, mental health, and social work. The clinic provides direct primary medical care for nearly 3,000 children a year who are without health insurance, access to medical providers and linking to specialists. Therefore, we do not anticipate any challenges in recruiting 95 youth between the ages of 12-15 over the three year recruitment period. The clinic is a bus with medical supplies and three medical exam rooms. Staff members travel with the bus across a 50 mile radius to serve communities with the highest percentage of children living in poverty and/or likely to be uninsured. Specific communities that will continue to be served through this program include: Little Havana, Homestead, Florida City, Little Haiti/North Miami, Westchester, and North Dade. Most of the visited areas have a community center or school rooms that can be utilized for extra medical exam room space. Typically, each site can offer three rooms.
- **UHealth at Kendall.** This clinic is a part of the University of Miami Health System. UHealth at Kendall has more than 60 physicians and serves children in the S. Florida area, including general pediatrics.
- The **Ambulatory Care Center West Pediatrics at Jackson Memorial Hospital**. This clinic is located within the Jackson Memorial Health System. The Jackson Memorial Health System is governed by the Public Health Trust, a dedicated team of citizen volunteers acting on behalf of the Miami-Dade Board of County Commissioners. Jackson Health System consists of Jackson Memorial Hospital; multiple primary care and specialty care centers; a variety of school-based clinics serving elementary, middle and high schools; two long-term care nursing facilities; six Corrections Health Services clinics; a network of mental health facilities; Holtz Children's Hospital; Jackson Rehabilitation Hospital; Jackson Behavioral Health Hospital; Jackson North Medical Center, and; Jackson South Community Hospital. Jackson Memorial Hospital is an accredited, non-profit, tertiary care hospital and the major teaching facility for the University of Miami Leonard M. Miller School of Medicine. With more than 1,550 licensed beds, Jackson Memorial Hospital is a referral center, a magnet for medical research, and home to Ryder Trauma Center - the only adult and pediatric Level 1 trauma center in Miami-Dade County. Ambulatory Care Center West

Pediatrics at Jackson Memorial Hospital provides patients with comprehensive care in a variety of services including pediatric primary care, gynecology and obstetrics. The pediatric practice serves over 7,000 children and youth a year. The Ambulatory Care Center West has more than a dozen exam rooms for the pediatricians. Dr. Audrey Ofir is the Director of Ambulatory Pediatrics and has agreed to have the Ambulatory Care Center West Pediatrics at Jackson Memorial Hospital serve as a recruitment site for the proposed study.

- **Kidstown Pediatrics, LLC.** Kidstown Pediatrics, LLC, is located in a residential area 10 minutes outside of downtown Miami. It is housed in a multistory office building and has 2,000 square feet available for office space. Kidstown is a private practice that provides comprehensive primary care services for children of all ages. Specific treatments offered include HPV vaccination, medical care for asthma, treatment for ADD/ADHD, and other vaccinations. Emergency services are available 24 hours a day, 7 days a week, but it is generally open from 8:30am to evening, Monday through Friday. Dr. Margaret Okonkwo, a practicing and board certified pediatrician, is President of KidTown, LLC. Dr. Okonkwo has been in practice for more than 10 years and serves approximately 6,000 children and adolescents per year.
- **South Florida Pediatric Partners.** South Florida Pediatric Partners is a private pediatric practice. One of their clinics is directed by Dr. Carol Da Costa, a solo practitioner who has been part of the community for the last 15 years. She provides comprehensive pediatric primary care services for children of all ages. Dr. Da Costa serves over 100 Hispanic families per week and provides routine well-child care (e.g., vaccinations) as well as treatment for a range of childhood illnesses and symptoms. The clinic is open Monday-Friday 9am-5:30pm and two Saturdays per month. Patients also have access to an after-hours emergency line.
- **Borinquen Medical Centers.** The clinic started as a grass-roots community effort in an underserved part of Miami-Dade, but now has expanded and offers comprehensive primary health care, dental, and behavioral health care throughout the County. Borinquen's patient population is about half Hispanic. There are 8 pediatricians in Borinquen.
- **Primecare Family Centers.** Primecare is private organization in South Florida with 10 physicians, offering pediatrics and family and internal medicine.
- **ECC Pediatris.** This clinic is a private clinic that provides pediatric primary care services to children and adolescents in the Doral area.
- **Dr. Ileana Fuentes Clinic**. This clinic is a small private clinic offering pediatric services to children and adolescents.
- **Castro Pediatrics, LLC.** Castro Pediatrics LLC. Castro Pediatrics, LLC, is a private clinic in Miami that offers health services to youth.
- **Gables Pediatrics.** Gables Pediatrics at the Shops of Merrick Park is a private clinic in Coral Gables offering health care services to youth.
- **Belkys Bravo Pediatrics.** Belkys Bravo Pediatrics is a private clinic in the Miami area that offers health services to youth.
- **Pediatrics and Family Medicine Associates**. This clinic serves youth and families in the Doral and surrounding areas.
- **Dr. Rene Lopez-Guerrero**. Dr. Lopez-Guerrero's Clinic is located in Miami and serves youth of all ages.
- **Dr. DeChurch Clinic.** This is a private clinic run by Dr. Stephanie DeChurch located in Miami serving youth.

- **Dr. Francisco E. Martinez Clinic**. Dr. Martinez's clinic serves pediatric patients in the S. Florida area.

23) Prior Approvals

This study was approved on 6/14/2016.

24) Recruitment Methods

Participants will be recruited from either the University of Miami Pediatric Mobile Clinic, Ambulatory Care Center West Pediatrics at Jackson Memorial Hospital, UHealth Pediatrics at the Professional Arts Center, or Da Costa Pediatrics (see #7 above for information about recruitment; see #22 above for a description of the clinics).

25) Local Number of Subjects

Approximately 650 participants (325 families) will be screened, and 190 (95 families) will be enrolled.

26) Confidentiality

The issues surrounding confidentiality are of supreme importance and sensitivity because personal information will be obtained from participants. Participants will sign a statement attesting to their understanding that the information they provide will be held as personal and confidential. To ensure confidentiality, all information will be coded so that it cannot be associated with any individual. A master sheet, with individual names and their respective code numbers will be kept in a locked file. All data entered into the computerized database will be identifiable by subject code number only. No one other than study staff members (under the supervision of study investigators) will have access to records identifying subjects' names at any time. All audio and video recordings will be stored in a locked filing video system located in our offices only accessible to study staff. These files will not be labeled with participants' names but with the code numbers assigned to them at the beginning of the study. Participant first names only are used in audio recordings and they will be removed upon transcription such that all final transcripts are labeled only with participant numbers. Audio files sent to the National Captioning Institute will be sent using a Secure File Transfer Protocol (SFTP) that enables secure file transfer capabilities between networked hosts. The have 2 SFTP servers available running Filezilla. They will provide me with an exclusive user account and password to a folder on the servers with restricted permissions to your account. All information gathered will be used only for scientific, educational, or instructional purposes.

27) Provisions to Protect the Privacy Interests of Subjects

During the recruitment and consent/assent process, and prior to any data collection, participants will be assured that their information is private, confidential, and will only be stored on internal University of Miami servers and accessed by study staff members. As described in #26 above, participants will be each assigned a unique code number to further protect their identity. Participants will be encouraged to ask questions during

the consent process and will be provided with contact information for the lead study investigators as well as for the University of Miami's Human Subjects Research office.

28) **Compensation for Research-Related Injury**

NA – research does not involve more than minimal risk

29) **Economic Burden to Subjects**

NA – other than costs associated with transportation to and from data collection appointments, participants will not be responsible for any costs because of participation in the research

30) **Consent Process**

For Aim 2: Study staff members will screen interested families remotely and confirm adolescents' eligibility by measuring their height and weight in-person. Prior to data collection, study staff will present and review the consent form to the caregivers who are eligible to participate based on the inclusion/ exclusion criteria. The consent process will take place in-person or remotely via videoconference on e-consenting using REDCap. After the caregivers understand the study and after all questions have been answered to their satisfaction, individuals who elect to participate in the study will be asked to sign the consent form. The consent process will last approximately 30 minutes, but it may take caregivers more or less time depending on how clearly they comprehend study procedures. Participants will electronically sign and date the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. An electronic copy of the informed consent document will be given to the participants for their records. If a parent is not available to complete consent, a legal guardian will be allowed to provide permission for the adolescent to assent. A legal guardian is a step mother or step father, or another person who has obtained legal rights to the adolescent. During the recruitment screening process, study staff members will determine if the primary caregiver is a legal guardian based on the provision of appropriate documentation.

For non-English speaking participants, consent forms will be made available in Spanish. Consent forms have been translated, back-translated and pilot tested for understanding in past studies conducted by the study investigators.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception) – Waiver of consent documentation will be requested for recruitment purposes.

Prior to formal consenting/assenting procedures, parents and adolescents will provide verbal consent to have the adolescents' height and weight measured by study staff to confirm their eligibility. Height will be measured using a stadiometer and weight will be measured using a digital or bioimpedance scale. Once participants formally consent for the study, parents will also have their height and weight measured and recorded.

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Participants who are not yet adults, including adolescents ages 12-15 participating in the present study will go through a similar process as their parents. Their age will be confirmed with the pediatric clinic and/or the primary caregiver. After the parent or primary caregiver has consented, study staff members will present the assent forms to the adolescent. We will ask caregivers to give the adolescent privacy to prevent the adolescents from being coerced to participate. The assent process will last approximately 30 minutes, but it may take youth more or less time depending on how clearly they comprehend study procedures.

Cognitively Impaired Adults - NA

Adults Unable to Consent – NA

Authorization for Use and Disclosure of Protected Health Information (HIPAA)

Patient medical records are being access for consent to contact and request is for a waiver of the requirement for written authorization from the patients to access their medical records.

Confirm that you will destroy the Protected Health Information (PHI) you and/or your Study Team acquire receive from JHS and/or UHealth at the earliest opportunity.

☒ ***I confirm***

Confirm that the Protected Health Inform (PHI) you acquire from JHS and/or UHealth will not be re-used or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible.

☒ ***I confirm***

31) Process to Document Consent in Writing

This study will be following "SOP: Written Documentation of Consent (HRP-091) with the exception of procedures described above to determine eligibility." Consent forms have been uploaded for review.

32) Drugs or Devices

NA – no drugs or devices are being tested in this study.