Study Protocol

The Impact of a Parenting Intervention on Latino Youth Health Behaviors (FPNG+)

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Introduction

The NIMHD-funded Families Preparing the New Generation (FPNG) is a 10-workshop *efficacious parenting intervention* to increase parent-child communication and family functioning as a means to prevent substance use in Latino youth.[1,2] Each parent workshop is 2.5 hours in length and is usually offered on a weekly basis. Based upon feedback from FPNG community partners, there is a pressing need to integrate healthy nutrition into the FPNG curriculum in order to make a greater impact on the health needs of Latino youth. Thus, the *overall objective* of the current application is to build upon the success of FPNG to promote healthy nutrition and reduce substance use among Latino youth. Our *long term-goal* is to help reduce health disparities observed among Latino youth through culturally grounded interventions that target nutrition as well as the prevention of tobacco use and other substances. Our *central hypothesis* is that by strengthening the parent-child communication and family functioning, it is possible to simultaneously impact two health behaviors (nutrition and substance use) among Latino youth and positively improve multiple health outcomes.

The proposed study will extend the scope of FPNG by creating an enhanced parenting intervention (*FPNG+*) that will promote healthy nutrition while sustaining its efficaciousness in youth substance use prevention using an ecological framework. The first phase of the proposed study will use a community-based participatory research (CBPR) approach[3] in partnership with Latino communities to extend the scope of the FPNG intervention and identify culturally-acceptable ways to weave nutrition improvement strategies into the existing parenting intervention. This will allow us to address multi-level social determinants of health that are common to substance use prevention and healthy nutrition promotion. The second phase will test the efficacy of the enhanced intervention over time through a 3-arm randomized controlled trial comparing FPNG+ (substance use prevention and healthy nutrition), FPNG (substance use prevention only), and a comparison condition (focusing on academic success). The transdisciplinary team will have a CBPR orientation and will apply qualitative methods, survey research methods, and biomarkers to measure change in nutrition and substance use outcomes over time among youth and parents.

Study design

In this 3-arm randomized controlled trial (RCT), parent-child dyads will be assigned to a 10-week group-based intervention, delivered to parents, targeting adolescent substance use prevention and diet improvement through parenting and family-focused strategies. The proposed study will be conducted in partnership with our longtime research collaborator, the ADA. ADA has a demonstrated record of successfully recruiting and retaining thousands of Mexican heritage and other Latino parents into *Realizing the American Dream* (RAD), their academic success program with no substance use prevention or nutrition content. ADA's trained community facilitators will lead the parents' groups (15 parents per group) via three conditions: substance use prevention and healthy nutrition (FPNG+; n=498 parent-child dyads); substance use prevention only (FPNG; n=498 parent-child dyads), or a comparison condition (RAD; n=498 parent-child dyads). The three curricula will be delivered through ADA programming, offered to families of 6^{th} – 8^{th} grade students (11-14 years old) in 18 different schools (6 per condition). Randomization will occur at the school level, each school randomly assigned to one of the three conditions. Participants will be consented for the specific condition their school is randomized to (i.e. the consenting materials will only describe the condition the school is assigned to).

Participant recruitment

We will recruit parent-child dyads consisting of one parent and one youth enrolled in 6th, 7th or 8th grade. Following inclusiveness policies from our community partner, the American Dream Academy (ADA), parents of children enrolled in other grades will also be included if interested in the program, but their children will not be part of the study. Inclusion criteria are as follows:
Youth:

- ages 11-14
- enrolled in 6th -8th grade at the time of recruitment from the ADA programs

Adults:

- age 18 or older
- parent/caregiver/guardian of an eligible youth or parent of a child enrolled in participating schools who expresses interest in the program

We will provide ADA with general "invitation scripts" to be used by the trained operators of the ADA phone call center describing the study and inviting parents and their children to attend an information session. Parents will be asked to bring their middle school grade child to the information session they attend. The next step in recruitment will be more targeted and will consist of phone calls to 6th-8th grade parents in an effort to maximize the number of participants with children in the target grades (6th, 7th, 8th). The ADA phone call center operators will read the script to parents according to the random assignment of each recruitment site. During the information session, trained bilingual study staff will provide an explanation of the study and answer questions prior to obtaining written consent. Parent-child dyads who are interested in participating will be asked to stay at the end for a consenting session during which the consent form will be read and explained, questions will be asked, and written consent, parental permission, and child assent will be collected. All parents of 6th, 7th , or 8th grade students will be asked to give their adolescent permission to participate in the study (data collection only). In addition, each youth will be invited to assent to each of the procedures, in addition to and separate from parental permission. We will not collect data from children who are not in 6th, 7th or 8th grades, even if their parents participate in the study. Participants will be enrolled in the study for approximately 8 months to allow for data collection and delivery of a 10-week intervention of individual workshops of 2.5 hours each. All data will be collected at baseline (T1), immediately post-intervention (T2), and at approximately 16 weeks post-intervention (T3). It is anticipated that a noteworthy majority of youth and adult participants will represent minority populations.

Self-identified Latino families (determined by their response on the survey question regarding ethnicity) with 6th, 7th or 8th grade children will be eligible to participate in an exploratory sub-study involving data collection through a home visit. To create the subsample of parents and youth who will participate in additional data collection for the exploratory aim, of those parents who choose to provide personal consent and child permission for surveys, for each of the three conditions, we will randomly select 9 self-identified Latino families per school (determined by their response on the survey question regarding ethnicity) to participate in all exploratory data collection procedures (finger prick; weight, height and blood pressure; 24 hour Food Recall; household food inventory). Because parents will have the choice to consent to these additional procedures, we will create a randomly selected mirror sample of an additional 9 self-identified families (determined by their response on the survey question regarding ethnicity) per school. If one of the original 9 parents chooses not to participate in these additional data collection procedures, we will randomly select a family from the mirror sample. This procedure will continue until we have 9 families per school (from each of all three conditions) who agree to participate

in all phases of data collection. Families in the mirror sample will not be contacted by the research team unless an original family chooses not to participate.

Data collection

Data collection from both parents and youth will take place at baseline (T1), immediately post-intervention at 10 weeks (T2), and at approximately 16 weeks post-intervention (T3). All parents and youth will be asked to complete a survey to collect information on substance use and nutrition outcomes (see Measures) regardless of intervention condition at the youth's school.

Additional data will be gathered from a random subsample of self-identified Latino 126 families (42 per condition) at the same time points (T1, T2 and T3) to explore the preliminary effects of FPNG+ on modifiable chronic disease risk factors and the home food environment (see Measures). This data collection home visit is anticipated to last 90 minutes during which the following procedures will take place: (1) measurement of parent and child body weight, height, and blood pressure; (2) collection of a finger prick blood sample from parent and child for measurement of HbA1c and total cholesterol using portable point-of-care devices; (3) and completion of a home food inventory to record availability of fruit, vegetables, and sugar-laden foods. Because blood will be collected from a finger prick, we will only collect the necessary amount of blood to perform the proposed analysis (three to four drops) on site by using it directly into the measuring device (similar to glucometers used by patients with diabetes). The reactive strips used with the measurement instruments will be discarded immediately after they are used. No blood samples will be stored. The 24 hour Food Recall questionnaire will be done over the phone for both parents and youth. As part of the 24 hour Food Recall, parents will answer a short questionnaire regarding some of the food details that their child may not know, such as the type of oil they buy, what kind of fat they use for cooking, and the types of bread and milk they typically buy for the family.

Measures

<u>*Survey.*</u> Self-administered surveys will be available in Spanish and English so the respondent can complete it in the language he/she chooses without needing to request the accommodation. If participants cannot read in either language, a Research Assistant will read the questions to them. All constructs will be measured at all three time points (T1, T2 and T3) with the exception of sociodemographic characteristics.

The survey will include items from our prior substance use prevention evaluations with Mexican heritage youth[4] supplemented by measures of participants' family functioning and cultural orientations. Outcomes include **recent use of substances** (amount and frequency of alcohol, cigarettes, marijuana, and inhalants),[5] **drug resistance strategies,**[6] **intake of fruit, vegetable, and sugar-laden foods**, assessed with the NCI *Dietary Screener Questionnaire*,[7] **family functioning,**[8] **familism,**[9] **parenting skills,**[10-15] **social support**,[16] **acculturation,**[17] **food insecurity,**[18,19] and **resiliency.**[20]

We will let parents and youth know, on the consent and assent forms, that we may need to contact them to clarify write-in answers on the NCI Dietary Screener Questionnaire. Specifically, participants are asked to write in the brand and type of cereals consumed and they sometimes provide ambiguous information (e.g., Kellogg's). Given that this information is needed to assess the overall dietary screener score, we will contact participants if their responses do not provide specific information about the type of cereal consumed.

Anthropometric measurements. **Body weight** and **height** of parents and youth will be collected in triplicate using light indoor clothing without shoes, using a standardized protocol. **BMI** for adults will be calculated in kg/m^2. For youth, weight and height will be used to determine BMI percentiles for age and sex based upon the 2000 CDC growth curves.

Cardiometabolic disease risk factors. Participants' (parents and youth) **blood pressure** will be measured in triplicate using an automated blood pressure monitor (Omron IntelliSense HEM-907XL; Omron Healthcare, Inc.; Bannockburn, IL). A finger prick blood sample will be collected from parents and youth to measure **total cholesterol** and **HbA1c**. This method was selected instead of venipuncture to reduce participant burden.

We decided to measure HbA1c as a marker of diabetes risk instead of fasting glucose to avoid the need for fasting blood sample collection. This will lower participant burden and increase our ability to collect samples from all participants in the subsample. Although it is recommended to measure fasting cholesterol to assess cardiovascular disease risk, it has been documented that non-fasting total cholesterol concentrations also predict cardiovascular events because concentration changes are minimal in response to normal food intake.[21] Similarly, fasting glucose may not be a robust indicator of type 2 diabetes risk in the pediatric population,[22] whereas HbA1c shows promise as a screening indicator for diabetes risk in youth.[23] Recently, HbA1c is been shown to prospectively predict the development of type 2 diabetes in youth[24] and may closely mirror dysglycemia under free-living physiologic conditions in youth.[25]

Detailed nutrition variables of interest (energy, macronutrients, consumption of sugar-sweetened beverages, added sugars, servings of fruits and vegetables, and whole grains) from youth and parents will be obtained using two 24-hour Food Recalls, conducted in either English or Spanish. Participants will be asked to recall all of the food they consumed in the past day.

Home food environment. We will use a modified version of the validated Home Food Inventory[26] to assess availability and variety of fruit, vegetables, sugar-containing foods and beverages, snack foods, and breakfast cereals in the home. Modifications included cultural adaptations to include foods commonly consumed by Latinos (e.g., *pan dulce*, papaya, cactus pads), and inclusion of breakfast cereals. Although this instrument was developed for self-report, we will utilize research staff for data collection to minimize self-report bias.

Data Management Plan

The data management goals are to ensure that (a) data are accurately collected, entered, and documented; (b) data are stored in an electronic format that will allow investigators to retrieve data easily and export data for statistical analysis; and (c) participant information remains confidential. Prior to data collection and entry, a codebook containing all variable names, descriptions, and value codes will be created. Only trained study personnel will have access to the data. Focus group and intervention data will be entered promptly after collection, and database entries from a random subset of 20% of the data will be audited to ensure data quality. We will conduct periodic data quality checks, including descriptive statistics. All study-related materials and data will be stored in locked cabinets or password-protected computers. Databases will only include de-identified data by using ID numbers only. Not sure if we should add something here about following up with them for the cereal question.

The PI, study coordinator, or a designated trained bilingual staff member will be responsible for explaining the study, answering questions, and obtaining written or verbal informed consent from parents and written assent from youth during information sessions at participating schools. Verbal consent from adults will be offered as an option only if the parent is interested and unable to attend in person to consent. Study personnel will reach out to them by phone. All procedures will be explained to potential participants in detail in their preferred language (English or Spanish). Special attention will be taken to properly explain the assent document in detail to youth to ensure comprehension. Consent and assent forms will be available in English and Spanish. Because randomization will occur at the school level, participants will be consented for the specific condition their school is randomized to (i.e. the consenting materials will only describe the condition the school is assigned to).

Data Analysis Plan

Power calculations considered design effects related to the clustering of outcome means by school sites. The total estimated sample size is 1494 parent-child dyads, across 18 schools. Based on data from the FPNG effectiveness trial, the level of clustering is low for our outcomes, including an intraclass correlation equal to 0.01, a student level R-square of 0.25, and a school level R-square of 0.03.[2] Because the effect size for substance use outcomes (*d*=0.20; FPNG vs. C) is lower than the expected effect size for nutrition outcomes (*d*=0.78; prior non-related intervention study), the total sample size is calculated for substance use outcomes. Accounting for these parameters, the power of this design is 0.802. For the subsample, the estimated sample size is 126 households across 18 schools – 7 per school. The average effect size of .69 is calculated based upon prior work on home food availability of vegetables, fruits, and desserts. Given the above stated parameters, the power of this design is 0.814.

All analyses will be conducted using multilevel analyses in Mplus,[27] with families clustered within schools. This analysis accounts for the clustering which, if uncorrected, may result in biased standard errors.[28] All analyses will employ a robust maximum likelihood estimator to adjust for any non-normality in the distributions of outcomes and to best control for Type I errors.[29] The analyses will also utilize full-information maximum likelihood (FIML)[30] to conduct intent-to-treat analyses that account and adjust for attrition and any item missing data.

We will use both baseline adjusted general linear model procedures (i.e., variants of multiple regression) and latent change modeling to test intervention efficacy. In all models, because the FPNG Plus is the intervention condition of interest, all analyses will use FPNG Plus as the reference group. The two remaining conditions (FPNG and Comparison) will be compared with the reference group. The first method will predict short-term (T2) and then long-term (T3) post-test outcome measures (e.g., adolescents substance use and diet outcomes), while controlling simultaneously for the baseline (T1) measure of the particular outcome. Latent-change models[31] will test whether and how changes over time in the outcomes differ significantly. Latent-change models will enable the assessment of change between T1 and T2 separately from change between T2 and T3. This examination will simultaneously test for improvements manifested during the course of the intervention (i.e., between T1 and T2) and for improvements maintained following the completion of the intervention (i.e., between T2 and T3). For mediation analyses, we will employ multivariate linear regression path analyses.[32,33] Each mediation model will test the indirect path between the intervention condition at T1 and outcome measures at T3 (e.g., adolescents substance use and nutrition outcomes) mediated through family functioning, parenting strategies, and parents' social support at T2. Mediation models will control for baseline (T1) measures of the particular mediator and outcome. We will employ a bias-corrected bootstrap approach to test the indirect effect.[34]

The moderation effects of sociocultural factors on outcome measures will be tested employing mean centered interactions of the measures of acculturation, acculturative stress, food insecurity, and resiliency with the dummy variable contrasts of intervention conditions, following Aiken & West (1991).[35] We will use baseline adjusted general linear model procedures to test for moderation. If significant moderation exists, we will use latent-change models to test whether and how changes over time in the outcomes differ significantly between adolescents who vary in the sociocultural moderating measures of interest (e.g., for those adolescents who are less and more acculturated).
Intervention effects on cardiometabolic risk factors and home food environment outcomes measured in the subsample will be tested through baseline adjusted regression models, including models that can appropriately analyze count data (e.g., Poisson, Negative Binomial). We will examine changes in short-term (T2) and long-term (T3) outcomes with dummy variable contrasts of intervention conditions, while controlling simultaneously for the baseline (T1) measure of the particular outcome.

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