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Study Title: Clearing the Path to Hispanic Children's Health

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<u>Clearing the Path to Hispanic Children's Health</u>
<u>- Statistical analyses plan</u>

Our central hypothesis is that participation in a 6-week community-based program will significantly increase: (a) healthy dietary behavior patterns and basic knowledge of nutrition; (b) physical activity levels; and (c) the organization of collective/shared family mealtimes. Consequently, excessive weight gain or weight rate among participant children will be slower compared to non-participants (control group).

Objectives and outcomes:

<u>Prevent excessive weight gain/maintain healthy weight in Hispanic children</u>. To assess the effect of the intervention on the **primary outcome** a measurement child BMI percentile that indicates stable weight, maintenance, or a negative change from the baseline in BMI percentiles in 6 to 18 year-old children.

The **secondary outcomes** include:

- ✓ Increased consumption of fruits, vegetables and legumes (at least by 0.5 serving)
- ✓ Reduced consumption of sugar-sweetened beverages (at least by 0.5 serving)
- ✓ Increased minutes of daily physical activity (at least by 10 min serving)
- ✓ Higher levels of family mealtime organization (increased organization for families in the intervention group)

Independent variables (parent and child unless otherwise stated):

- ✓ Education level
- ✓ Acculturation
- ✓ Food consumption patterns
- ✓ Social support

Data analysis

All analyses will be performed using Statistical Analysis Software (SAS®) version 9.3 or later (SAS® Institute, Cary, NC). All statistical tests will be two-sided tests using a 5% significance level. Age (years) will be calculated as (⌈date of informed consent – date of birth⌉ / 365.25). Demographic characteristics (e.g., age, sex), study outcomes and independent variables will be summarized overall, by treatment group (intervention and non-intervention control) and time point and separately for drop-outs, if applicable. Continuous variables will be summarized using n, mean, SD, median, minimum, and maximum. Categorical variables will be summarized using frequencies and corresponding percentages. Analysis of covariance (ANCOVA) or non-parametric methods may be used to compare continuous variables between treatment groups. Categorical variables will be compared using the Chi square test or Fisher's exact test. Correlations among the independent variables will be assessed using the Spearman correlation coefficient or other suitable correlation indices depending on data type.

<u>Primary analysis.</u> Comparisons of child BMI percentiles across treatment groups will be conducted using mixed modeling with random effects (time points nested within a child, child nested within family defined by at least one parent) and treatment*time interaction. Independent variables will be examined using scatter plots, and will be transformed if required. We assume that the population of interest is heterogenous, a mixture of different groups of individuals, depending on variations in the independent variables at baseline. To consider the non-independence of parent-child dyads, a Multilevel Mixture Model (MMM) will be used to identify the probability of a set of independent factors other than the participation in the program (intervention/control) affect the primary outcome of child BMI percentile (1). Parameters will

be inferred using maximum likelihood based techniques. The best fitting and most interpretable model will be selected. Two penalized model selection criteria, Bayesian Information Criterion and Akaike Information Criterion will be examined in order to pick the most parsimonious model (least number of parameters) to avoid over-fitting (2).

Secondary analysis. Secondary outcomes will be analyzed using techniques like the primary outcome. A mixture model will be specified at the parent level.

Tertiary analyses. Association of the independent variables with the outcomes will be determined using random effects mixed models. Associations among variables used for assessing food consumption patterns will be determined.

Potential pitfall and alternative approaches. In the event of highly correlated data, variable selection algorithms will be employed. Randomization will be used to break ties among competing factors.

Sample size and power calculations. We will recruit 50 families from each state site (Illinois, California, Iowa, Puerto Rico and Texas) for the intervention (n=250) and same number for the control group. We will randomly assign control and intervention groups, in total 500 families will participate in this multi-state project. At the end of the third survey at 6-months, control group participants will receive health-promotion material commonly distributed by Regional Extension offices. We will oversample by 5 families at each cycle in anticipation of participant attrition (each site will decide how many cycles will be needed to complete their target). The sample size was determined based on difference in the primary outcome observed in our previous study (3) for changes in food servings with all families participating in the workshops. According to our power calculations, even with an attrition rate of 20% per site we will still have a power 0.86 with alpha of 0.05 to identify differences in outcomes of specific food servings (1 serving per week of fruits, vegetables or legumes). We also evaluated that even when the overall project only recruits 109 families we will have 99% power at alpha of 0.01 to find a difference of one food serving (more/less) for outcomes related to fruit and vegetables. According to our power calculations, even with an attrition rate of 20% per site, we will still have a power 0.90 with alpha of 0.05 to identify obesity prevention or weight maintenance with focus on our **primary outcome** (child BMI percentile) between intervention and non-intervention controls.

Therefore, implementing culturally adapted interventions that modify behavior, increase nutrition practices with a systematic and sustained approach are important. The focus is on long-term sustainability and family support to improve wellness. It is expected that more projects, as proposed here, plan additional longitudinal research (beyond 6 or 12 months follow-up), to identify which children and adolescents profit better from a given intervention, and thus tailor specific and efficient approaches to prevent overweight or obesity in adulthood. The long-term, longitudinal type of studies -as necessary as they are to prove benefits- involve greater social and economic investment and a persistent contribution among stakeholders and funding agencies that are difficult to implement at this time. However, our team seeks to establish deep community liaisons to facilitate long-term follow-up with the participating families and involvement of new families, so the current proposal has sustainable benefits beyond termination of this grant.

REFERENCES

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3. Hammons AJ, Wiley AR, Fiese BH, Teran-Garcia M. Six-week Latino family prevention pilot program effectively promotes healthy behaviors and reduces obesogenic behaviors. J Nutr Educ Behav 2013;45(6):745-50.