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# A Mobile Phone Based Pilot Intervention to Prevent Obesity in Latino Preschool Children

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**Title:** A mobile phone pilot intervention to prevent obesity in Latino preschool children

**Conditions:**
Childhood obesity interventions
Mobile Health
Latino populations

**Eligibility Criteria:**

Eligibility criteria will include an adult female or male caregiver who(1) self-identifies as an individual of Latino descent; (2) has a 2- to 5-year-old child/grandchild (where the relationship does not have to be biological but caregiveis a legal guardian); (3) lives with child or grandchild or cares for child/grandchild at least 20 hours per week; speaks Spanish or English; (4) is fluent in English or Spanish; (5) owns a mobile smart phone; (6) is able and willing to receive and interact with text messages on parenting, dietary, and physical activity strategies for young children (focus group Aim1); or (7) has the ability and willingness to participate in a 4-week mHealth intervention (Specific Aim2) and complete baseline, 1-month, and 6-month post-baseline measurement protocols. The ability to participate will be determined by using of a Subject Comprehension and Participation Assessment Tool. Families will be excluded if the child has a failure to thrive diagnosis or medical conditions related to overweight status such as Prader-Willi Syndrome.

**Age Limit:**
Minimum age 2 yrs
Maximum no limit (N/A)

**PROTOCOL SYNOPSIS**

***Summary***

The study objective is to pilot a stand-alone 4-week mobile phone intervention with Latino mothers, fathers, and grandparents, geared at building caregiver strategies to support evidence-based and age appropriate dietary, media-viewing, and physical activity practices among 2- to 5-year old children in order to resolve key challenges of traditional in-person pediatric obesity interventions (e.g. transportation, time), and also leverage important determinants of Latino health (e.g. familism, language). The primary and secondary endpoints are reached when all family cohorts complete their 6-month post-baseline data collection procedures. The study population is biological or adoptive mothers, fathers, and grandmothers of 2-to-5-year old Latino children living in Los Angeles, California without failure to thrive diagnosis or medical complications associated with their weight status such as Prader-Willi Syndrome

A prospective randomized pilot study will be completed to assess acceptability, feasibility, and preliminary effect sizes on children's weight-related behaviors and BMI z-scores at 6 months post-intervention, in preparation for a larger randomized trial to evaluate the intervention's efficacy. The intervention will deliver 4 interactive texts every week for one month to Latino caregivers of 2 to 5-year old children and 2-months of mobile phone "booster" doses that incorporate behavioral change techniques using a group strategy, a cornerstone of many effective in-person parent-focused pediatric obesity interventions. The study will first use qualitative methods to maximize the acceptability and usability of the existing mobile phone group learning strategies with a small group of Latino mothers, fathers, and grandparents. A 4-week mobile phone pilot intervention will then be completed with 66 caregiver-child dyads recruited from two WIC sites in East Los Angeles. Eligible caregiver-child dyads will be randomly assigned into the 4-week mobile phone intervention condition or the comparison condition, in which caregivers receive usual WIC services. Acceptability and feasibility outcomes will include: (1) the number of families needed to be screened per month; (2) attrition rates of a randomized mobile phone intervention with Latino populations; (3) dose and exposure of texts; (4) frequency of sharing/replying to texts by caregiver-type; (5) number of completed baseline and follow-up data; and (6) family-centeredness of the intervention. Pre- and post- intervention data will be collected at baseline, 1-month, and 6-months after the intervention begins in order to estimate preliminary effect sizes and standard deviations associated with child dietary, physical activity, and media viewing practices and BMI scores. Mediators of the intervention will include measures of caregiver self-efficacy, caregiver feeding practices, and group support. The pilot study will provide the acceptability, feasibility, and preliminary data on child weigh-

related behaviors and BMI to develop an R01 proposal to test the intervention's effectiveness via a large randomized controlled trial.

**Recruitment and Retention**

The proposed research studies will include focus groups to maximize acceptability and usability of a 4-week childhood obesity mHealth intervention, followed by a pilot intervention research study to assess feasibility and preliminary outcomes of the 4-week mHealth intervention. The intervention's focus on weight-related behaviors during early childhood, requires the involvement and participation of child caregivers as the agents of change for child weight-related behaviors. The proposed research activities will, therefore, target mothers, fathers, grandmothers, and young children (2-5 years old).

Study participants (mothers, fathers, and grandmothers) will be recruited using recruitment fliers and learn about the study by making contact with study investigators. All participants will provide written informed consent to participate in the study. To ensure that potential participants understand the study and the activities he/she will be asked to complete, we will use a Subject Comprehension and Participation Assessment Tool to assist in this process. Children's assent or consent will not be obtained due to their young age (2-5 years old), although they may opt out. During consent procedures, participants will be given both written and verbal (in Spanish and English) information about the study to address low-literacy levels or limited English proficiency. Only legal guardians of a child will provide consent for the study, and non-legal guardians will excluded. Participants will be told and given information relating to all the potential risks of study involvement, including the potential for loss of privacy and the ethical obligation of researchers to report observed neglectful or abusive behaviors. All protocols for recruitment and informed consent will be vetted with our community partner, WIC, and included in our UCLA IRB application.

Bilingual and bi-cultural research assistants will be trained and supervised by the research team (PI and Co-Is) and will be responsible for recruiting, screening, and consenting potential participants. We will propose distributing recruitment flyers explaining the study as families visit WIC centers. These recruitment flyers will be made available in English and Spanish and written at a 6th-grade reading level to ensure the information about the research activities are clear and understandable. A mother, father, or grandmother who cares for a child who is between the ages of 2 – 5 years old who expresses an interest in the study, will be instructed in the flyer to contact project staff, who will explain the study and invite the families to participate in the study. If introductory letters are not found to be effective for recruitment, we will recruit potential participants in person.

For the focus group study (Specific Aim1) each caregiver, will be asked to complete one focus group session. Monetary incentives for participation will be comparable to amounts used in other research activities in the community, a $25 gift certificate for focus group participation. For the mHealth pilot intervention activities, mothers, fathers, and grandmothers will be asked to participate in a 4-week mobile phone intervention to build caregiver knowledge and skills related to healthy weight-behaviors for young children (Specific Aim 2). We will use similar recruiting strategies used for Specific Aim1 where potential parents will be recruited from community centers. Recruitment strategies will have a goal of enrolling equal numbers of mothers, fathers, and grandmothers. If recruitment flyers to encourage study participation do not yield the number of required participants, we may recruit participants' in-person at WIC centers waiting rooms. Monetary incentives for all data collection points will be provided to retain participants in the study. We will use amounts comparable to other research activities in the community, a $25 gift card for each data collection point. In addition, if follow-up measurement appointments at the 6-month data collection points are low we may also explore a higher incentive amount to minimize attrition ($35).

**DATA and SAFETY MONITORING PLAN**

Data Safeguarding.

The qualitative and quantitative research methods of the proposed studies will not involve the collection of biological samples or the use of drugs. The data collection activities of the proposed studies all constitute minimal-risk procedures. As such, there is no need to convene a formal data safety monitoring board but the study will include a Safety Officer. The PI, Dr. Guerrero, and the Safety Officer will have ultimate responsibility for data safeguarding. Dr. Guerrero will be responsible for day-to-day oversight of the data collection and data management, training the data collection team in data safeguarding techniques, and oversight of all staff who handle participant-identifying computer files, surveys, tracking forms, and other identifiable data. All research assistants and staff involved in data collection or handling of data, will receive training that addresses data safeguarding and confidentiality, and will sign confidentiality agreements. Raw data in need of safeguarding

will include files generated to link identifying information with ID numbers and consent forms that will include participant name and unique ID. These raw data files will be stored in separate secure locations (encrypted data file on a password-protected desktop within my locked office and locked file cabinets within my locked office). The master code list and all raw data files will be destroyed once all data collection is completed and analyzed.

Monitoring and Processes for Adverse Events.

We do not expect that participants will experience adverse events. Although unlikely, if during our research studies with family caregivers we observe neglect, abuse, or a situation that is otherwise dangerous for children, we would ethically have to report such an observation to a higher authority such as Child Protective Services. For any other adverse event, staff will inform the Principal Investigator who will also communicate the adverse event to the study Safety Officer and then appropriate services and authorities (e.g. police, medical services, UCLA Office of the Human Research Protection Program) and request assistance. In all instances of adverse events, an Adverse Events incident report will be written and submitted to the UCLA Office of the Human Research Protection Program by the Principal Investigator. In addition, the funding agency and appropriate authority/ies will also be informed by the Principal Investigator. All phases of the study will be reviewed by the UCLA Office of the Human Research Protection Program.

**Analysis Plan**

Data Analysis Aim 1

Focus groups will be professionally transcribed and translated. The PI and Co-Is, Drs. Ayala and Ramirez, will independently synthesize and organize the qualitative data into the ***a priori*** domains of acceptability and usability mentioned above, and identify any emergent themes. The PI and Co-Is will then meet to iteratively discuss and resolve differences by consensus. Focus groups will be used to analyze the following domains related to acceptability and usability: (1) identify preferred linguistic and culturally appropriate terms and images; (2) acceptability of sharing text, pictures, videos, and audio to support group learning; (3) preferred strategies for learning; (4) ease of using interactive texts; and (5) ease of completing interactive tasks.

Data Analysis Aim 2.

Acceptability and feasibility will be analyzed using scores on the adapted HRSA MCHB Family-Centered Care items and the implementation and evaluation framework measures. Feasibility indicators will be evaluated against ***a priori*** criteria from the literature,[63,66,67] providing a roadmap to evaluate "success" and whether to move forward with an R01 randomized clinical trial. Analyses of data from measures of children's weight-related behaviors and BMI, as well as care-giver data will be done using Stata 15.0 software. Means and frequencies of outcome variables will be done for both the intervention and control group. T-tests and chi-square tests will evaluate for group differences on baseline characteristics. Mixed effects linear regression models will be used to analyze the intervention's effect on the outcomes of child behaviors and BMI score over time (baseline, 1- and 6-month post-baseline). These models will include intervention status, baseline dietary, physical activity, media-viewing behaviors, and BMI score, and selected covariates given the sample size. Furthermore, caregiver feeding practices and acculturation will be evaluated as potential moderators of intervention effects on child outcomes. Group Cohesion will be analyzed using scores on the adapted Physical Activity Group Environment Questionnaire[60] and analyzing participant shared content using Linguistic Inquiry and Word Count software and theme taxonomies as used in other online support group studies[64,65] These variables, will be examined to evaluate the extent to which they function as potential mediators of child BMI outcomes.