Promoting The Self-Regulation of Energy Intake in Latino Preschoolers: A Family Focused Obesity Prevention Program

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STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

BACKGROUND AND RATIONALE

Childhood overweight and obesity have increased significantly in the past 3 decades.[1] Rates of overweight in the US have more than doubled in younger children; more than 26% of preschool aged children are currently overweight or obese.[2] Obese children are at an increased risk for poor socio-emotional development and problematic medical conditions.[3] During the first 5 years of life, an increase in weight velocity from 2 to 5 years is the strongest predictor of obesity in early adulthood.[4] Childhood obesity rates are particularly high in low-income, minority populations.[2] Targeting young children and their families from high-risk groups may help to curb the obesity epidemic.

During the first 5 years of life, children learn what, when and how much to eat and what foods they prefer.[5] Programs developed to prevent childhood obesity in school aged children have had moderate success and limited long term impact.[6-8] The focus on school age children instead of early in life and the lack of inclusion of parents and the family may diminish sustainability of behavior change in these programs. The current study will develop and evaluate a novel approach to obesity prevention that will incorporate the family and focus on the self-regulation of eating in young children. The primary goal of the study will be to encourage and assist parents in recognizing and supporting their children to pay attention to their internal cues of fullness and satiety.

Experimental studies with preschoolers can inform childhood obesity prevention efforts at an early age. Preschool children have the ability to regulate energy intake during meals[9,10] and across successive meals over 24-hours[11] by starting and stopping eating in response to internal cues of hunger and fullness. Additionally, though intake at meals was considerably variable, total daily energy intake was tightly regulated.[11,12] Older children showed poorer compensation compared to younger children; thus, children may lose this ability as they grow older.[13,14] Individual differences in this ability have been linked to feeding behaviors. For example, parents who reported higher control in feeding had children who showed a lessened ability to self-regulate their eating.[15] Feeding practices, such as encouraging eating when the child is not hungry, providing inadequate exposure to novel foods, and serving excessive portion sizes, may deter children from attending to internal fullness cues.

Individual differences in child eating self-regulation have been linked to child weight.[15-17] Eating

in absence of hunger (EAH) was associated with higher child and adolescent weight[18-21] and poor satiety responsiveness was associated with greater weight status among children ages 3-11.[22-24] Children with poorer eating self-regulation are at a greater risk for childhood obesity.

Experimental studies show how children come to prefer novel foods. When exposing young children to novel foods, an effect of the amount of exposure on choice and liking was shown.[25,26] It took 8 to 15 or more exposures for children to learn to prefer novel foods[25] with results being replicated in a social marketing study[27] and more naturalistic settings.[28] Exposing children to novel foods may increase willingness to consume foods such as vegetables; however, most parents stop serving new foods to children considerably short of the 8 to 15 recommended exposures.[27,29]

Experimental studies on portion sizes have implications for childhood obesity. Children seen in conditions of varying entrée portion size and energy content ate 34% more calories at a single meal when served a larger, more energy-dense portion.[30] When serving children 3 main entrees and a snack over a 24-hour period, total energy intake was 140 kcal greater or 12% higher in the large portion condition (double the reference size) relative to the reference condition.[31] In an observational study in a naturalistic setting, the average kcal of food parents served their preschool children for dinner (median = 565 kcal) was greater than the average kcal of food parents consumed themselves during the same meal (median = 547 kcal).[32] The amount served to the child was significantly associated with the amount consumed ($r = 0.88$). Large portions typically served to young children may contribute to childhood obesity.

Routines and structure are associated with better child outcomes; thus home eating routines may be important in creating family structure that supports healthful child eating.[33,34] Preschool children experiencing 3 common household routines which included family dinners had a 40% lower prevalence of obesity.[35] Unconscious drivers of food choice and intake are also prevalent in the larger environment (food advertising, billboards, arrangement of food in the grocery store) which may encourage food choices without reasoned awareness of the long term impact on childhood obesity.[36]

It should be noted that numerous programs have been developed to prevent obesity in children, mostly in school settings. Some of these programs have had moderate success;[6,8] however, the growing consensus is that they are of limited effectiveness for the following reasons: 1) interventions during the school years do not address child eating patterns developed early in life; 2) interventions that do not involve parents or families limit the sustainability of behavior change; and 3) interventions that focus on only nutrition education and physical activity neglect important parental feeding behaviors that can reduce the likelihood of childhood obesity (e.g., encouraging preferences for healthy foods, facilitating self-regulation of energy intake, serving appropriate child-sized portions, establishing mealtime routines, and addressing food cues in the larger environment). Although researchers have begun to develop, evaluate, and disseminate family-based obesity prevention programs,[5,37,38] few comprehensive obesity prevention programs currently exist that focus on the role that parents play in the development of children's food preferences, food selection, and self-regulation of energy intake. Additionally, even fewer programs currently exist for preschoolers designed to specifically address the needs of low-income, minority families.[7]

The Strategies for Effective Eating Development—SEEDS prevention program will add to the field by focusing on the role parents play in the development of child food preferences, food selection, and self-regulation of energy intake—known risk factors for childhood obesity in low-income families with preschoolers. To our knowledge, there are currently no prevention programs that address these issues in low-income families. SEEDS will incorporate a dialogue approach to adult learning[39] and a well-known theoretical approach for behavior change—Self Determination Theory.[40] The child curriculum will focus specifically on developing food preferences, and encouraging self-regulation of energy intake. These same issues will be targeted in the parent curriculum along with other parenting behaviors associated with child weight status (serving appropriate child-sized portions, establishing mealtime routines, and addressing food cues in the environment). Fostering behavior change by delivering similar content to both parents and children is expected to increase program impact.

STUDY OBJECTIVE

The goal of this study is to develop and test the efficacy of a scientifically-based, culturally competent seven-session parent directed, obesity prevention program focused on parental feeding strategies that support young children's self-regulation of intake.

STUDY DESIGN

A randomized controlled trial will be implemented across 2 sites (Houston, an urban city in Texas; and Pasco, an agricultural community in Washington) to examine the efficacy of the SEEDS childhood obesity prevention program. The prevention arm will receive parent and child program curriculums separately over 7 weeks for a total of 7 lessons. One lesson will be held each week with parent and child lessons held simultaneously. Each lesson will last about an hour. A combined family lesson (parent and child together) will be held before the parent and child lessons. All lessons will be held after the school day in Spanish at Head Start centers in Houston, TX and similar early education centers in Pasco, WA. The control arm will receive no curriculum. Approximately 8 to 10 families will participate in each of the prevention and control conditions at each wave. Parents will be asked if they could read and write in English or Spanish during eligibility screening so that assistance can be made available at the data collection sessions for those who need help completing the questionnaires. Participants in the prevention and control arms will complete the same assessments prior to the prevention program (pretest), after the program (posttest), and at 6- and 12-month follow-ups. Participants will be compensated $40 at pretest, $50 at posttest, $60 at 6 months, and $85 at 12 months.

FACILITATORS

Bilingual staff members will lead the face-to-face groups (i.e., parent, child, and family lessons). Parent facilitators will be required to have a graduate degree in psychology or education to optimize behavior change that is integrated into the program content. Child facilitators will be required to have training or experience in early childhood education. Family lessons will be co-facilitated by the parent and child facilitators. Facilitator training will include a 2-day intensive training session guided by study investigators which will include coverage of the program

content, delivery of the lessons in practice sessions, and training to maximize participant engagement and involvement based on education principles. These principles will be reinforced during 2 follow-up training sessions to be held for the facilitators throughout the randomized controlled trial. These follow-up training sessions will include maintaining intervention fidelity and discussions regarding challenging questions or comments from parents that the facilitators experienced and ways to address them.

ASSESSMENT STAFF

A separate set of bi-lingual staff blind to the conditions (prevention and control) will be hired and trained to conduct assessments. An undergraduate or master's level degree will be required. To ensure consistency in training, all assessment staff will attend intensive training.

PARTICIPANT ELIGIBILITY AND RECRUITMENT

Families (parent/child dyads) will be recruited from Head Start centers in Houston, Texas and childcare centers serving families with low incomes in Pasco, Washington. The Pasco centers will be similar to Head Start in that they provide free services and support for families with low incomes. The goal of these centers is to ensure that all children enter kindergarten ready to succeed. Children who are 3 to 5 years of age with their parent identifying as Hispanic will be considered eligible. Exclusion criteria include: parent under the age of 18 and parent and/or child had major food allergies, diabetes, or were on special diets, including those who were vegetarian. Upon completion of pretest assessments, the project coordinator at each site will use a computer-based randomization tool to assign participants to 1 of 2 arms using simple randomization. Research staff members will work closely with the child development centers regarding recruitment procedures. Recruitment activities will be conducted during registration of children at the centers, parent meetings and drop off and pick up times. Specifically, research staff will explain the goal and activities of the study to interested parents and parents will complete informed consent procedures should they choose to participate in the study. The parent who is primarily involved in feeding the preschool child will be designated as the target parent. The study will be reviewed and approved by the Institutional Review Boards at Baylor College of Medicine and Washington State University. Parents will provide informed consent for themselves and their children before taking part in the study and assent will be obtained from the children as well.

PROGRAM FIDELITY

Observers trained in the curriculum content will conduct fidelity observations on 40% of the lessons. Based upon observer availability, the observations will be distributed across parent, child and family sessions. Facilitators will not be notified in advance that they would be observed. Observers will be different from the facilitators delivering the curriculum. Fidelity will be defined as the number of 'yes' responses reported by the observer (signifying that the facilitator adhered to the lesson component as described in the curriculum) divided by the total number of possible responses (i.e., yes, some, and no).

MEASURES

Data collections for both the prevention and control arms will be conducted in small group settings led by trained staff members of Hispanic descent who are proficient in reading, speaking, and writing in English and Spanish. Data collectors will be blinded to participant group allocation. For parents with low literacy skills, data collectors will read the questions to the parents and recorded their responses. Child assessments will be completed at the same time as the parents in a separate room. Most measures are validated for use with preschoolers and Hispanic samples.

Parent Feeding Measures (Practices, Styles, and Knowledge)

Food Parenting Inventory (FPI). The FPI is a parent-report measure of feeding *practices* with 16 subscales assessing 3 higher level feeding constructs: 1) Encourage Trying New Foods (offer new foods, encourage exploration of new foods, urge child to eat new foods, and repeated presentation of new foods), 2) Mealtime Structure (family meals, regular timing of meals and snacks, inconsistent mealtimes, indifferent feeding, child involvement in food preparation, parent decides portion sizes, and serving measured portions) and 3) External Control (pressure to eat, restriction, food as reward, responsiveness to child's fullness cues, and monitoring).[41]

Caregiver's Feeding Styles Questionnaire (CFSQ). The CFSQ is a parent-report questionnaire developed to measure feeding *styles* in parents with low incomes.[42] The questionnaire was developed for use with parents of children ages 3 to 11. Parents indicate how often they use 7 child-centered (e.g., reasoning, complimenting) and 12 parent-centered (e.g., demands, threats) feeding directives. Two feeding style dimension scores of demandingness and responsiveness are derived from the child-centered and parent-centered items. Parents are classified into 4 feeding style categories of authoritarian, authoritative, indulgent, and uninvolved. Evidence of test-retest reliability, internal consistency, convergent and predictive validity has been demonstrated in Hispanic samples and samples with low incomes.[42-44]

Feeding Knowledge Questionnaire (FKQ). The FKQ was developed for the current study to assess the degree to which parents learned the program content. Forty items measure the main messages of the program. Sixteen items refer to 'best practices' feeding *knowledge,*11 items refer to common misconceptions about feeding, and 11 questions measure parents' efficacy about feeding their child. Other program content is measured as well: 1) exposure to new foods and 2) child and parent roles during feeding.

Child Eating Behavior Measures (Self-regulation, Trying New Foods, and Fruit and Vegetable Consumption)

Compensation Protocol. Observed trials of children's response to changes in energy density in a meal (compensation trials) will be used to assess child *eating self-regulation*.[15] On 2 separate days, children will participate in a two-part meal consisting of 1 of 2 versions of a "drink preload" and a standard meal. On each day, the drink preload will be either high (152 kcal) or low (3 kcal) in energy. The standard meal, containing about 595 calories or 40% of the daily food requirements for 3- to 5-year-olds, will be served 30 minutes later. Consumption will be measured by weighing the foods prior to and after the standard meal based on manufacturers'

information.[15,46] An eating self-regulation score (COMPX) will be calculated by determining how each child adjusted his/her intake at the meal based upon the 2 preloads. COMPX has been used successfully to evaluate an intervention to improve children's self-regulation of energy intake.[47] This measure has been used with preschool aged children;[48] it has not been used previously with Hispanic samples.

Eating in the Absence of Hunger (EAH). Child *eating self-regulation* will also be measured by the EAH task developed by Fisher and Birch.[49] On the day the child receives the high energy preload drink as part of the compensation task and approximately 10-15 minutes after finishing the standard meal, the child will be presented with sweet and savory snacks along with age appropriate toys. Children will be left with the food and toys for 10 minutes and will be told they can eat what they want, sit quietly, and/or play with the toys. This task will be administered in the centers to several children at once, although children will complete the task individually through the use of portable screens creating a separate assessment area for each child. Remaining snacks will be measured and total kcal consumed will be calculated. Scores will reflect the total number of kcal eaten in the absence of hunger. This assessment has been used predominately with White children and has been validated with preschoolers; a few studies have used the EAH task with Hispanic children.[50]

Child Eating Behavior Questionnaire (CEBQ). The CEBQ is a parent-report measure assessing 8 dimensions of child eating behaviors.[51] Validity and reliability have been demonstrated.[51] For this study, only the subscales of food responsiveness, emotional overeating, and satiety responsiveness are targeted because they are considered parent-report measures of child eating behaviors related to eating self-regulation. The CEBQ has shown adequate validity and reliability[51] and has been used successfully with Hispanic parents of preschoolers with low-income levels.[52]

Child Tasting Panel Observation. A standardized food tasting protocol, developed by Sullivan and Birch[53] and modified by Moding, Bellows, Grimm, & Johnson,[54] will be administered to measure taste preferences (Yummy, Just OK, or Yucky) and children's willingness to try new foods (1 = tried; 0 = refused). Each child will be asked to try bite-sized samples of 9 familiar and novel foods from a variety of food groups including broccoli, beets, couscous, garbanzo beans, gouda cheese, grapefruit, kale, okra, and papaya. Each food will be served in a small two-ounce cup and include 3 small pieces of the food. This assessment tool was developed for a large, 3-year longitudinal study of preschoolers in Colorado (41% Hispanic).[54]

Food Preferences Questionnaire (FPQ). The variety of fruit and vegetables consumed by the children will be measured by a food preference questionnaire adapted from Skinner and colleagues.[29] Parents will report on their child's food consumption from 112 food and drink items using 3 categories: never tried it, tried – liked it, or tried – did not like it. Similar measures have been used successfully by the Food and Drug Administration in the Total Diet Study.[29] Only data on the fruit and vegetables will be analyzed given the program emphasis on trying fruit and vegetables, and the fact that the vast majority of foods in the questionnaire are fruit and vegetables. Two measures will be examined: the total number of vegetables tried out of 50 and the total number of fruits tried out of 27. This questionnaire has been used predominately with White samples.[29]

Anthropometrics. Trained staff, following standardized procedures, will measure parent and child heights (to the nearest 0.1 cm) and weights (to the nearest 0.1 kg).[55] Two height and weight measures will be averaged for each parent and child. Age- and gender-specific BMI z-scores for each child will be calculated. Children will be classified into healthy weight (5th to < 85th percentile), overweight (≥ 85th to < 95th percentile), and obese (≥ 95th percentile) according to Centers for Disease Control and Prevention standards.[56] BMI scores will be calculated for the parent and classified as low and normal weight (BMI < 24.9), overweight (BMI ≥ 25 to <30) or obese (BMI ≥ 30).

DATA ANALYSES

All analyses will be intention-to-treat analyses—that is, data from parents and children will be analyzed based upon the condition to which they will be initially assigned, regardless of the number of classes they attended. This approach, although it reduces power, maintains the internal validity of the RCT design.[57] Because participants will be nested within classes, the intraclass correlations (ICC's) will be first examined for each dependent variable to determine if a statistical approach controlling for such nesting will be necessary. All outcome variables (except for child weight status) will be examined using multilevel analyses with the SPSS (version 25) Mixed Models Program. The SPSS Mixed Model program does not provide measures of effect sizes; however, 95% confidence intervals will be included for precision. Child sex, child age in months, and child BMI*z* at pre-test will be control variables in all of the multilevel analyses. Significant condition by time interactions will be followed up with simple main effects analyses and multi-level analyses comparing pairs of time points. The main analyses will be conducted on participants who have data at all 4 time points. Paired comparisons will use all available data. Most of the missing data will be addressed by calculating the subscale scores using the mean of the non-missing items in that particular subscale. If greater than 25% of a subscale's items are blank, then the score will be considered missing. The multilevel models also will be rerun examining (1 at a time) possible program moderators: child age, child sex, child BMI status, and location (Houston versus Pasco). Moderation will be tested by examining the significance of the moderator by condition by time interactions.

Finally, to examine dosage effects, the multilevel analyses will be rerun for those variables showing significant condition by time interactions. In these analyses, only data from parents in the prevention conduction at post-test, 6-months, and 12-months will be examined to determine if the number of sessions parents attended predict their subsequent responses on questionnaire assessments (the pre-test assessments will not be included in these analyses because these sessions occurred *before* parents attend any classes). In conducting these analyses, the condition variable will be replaced by a variable assessing the number of lessons attended (values ranging from 0 to 7). To determine if the dosage effects vary by time point, a separate set of analyses will include the "lessons attended by time" interaction as a predictor (along with the corresponding main effects).

A multinomial logistic regression will be used to examine the effects of the program on children's BMI category (i.e., healthy weight, overweight, and obese). This regression will examine the main effect of condition, controlling for the same variables as in the multilevel

analyses (i.e., child sex, child age in months, and child BMI *z*-score at pretest).

To control for Type I error, the critical *p* values for each assessment will be determined with the unweighted Bonferroni method,[58] dividing the critical value of $p < .05$ by the number of comparisons conducted for a given assessment. As discussed in Shaffer,[58] corrections for familywise error involve correcting alphas separately for each family of hypotheses. Although defining families is a rather straightforward process in a simple experiment (e.g., 1 family in a study with a single dependent variable and 1 independent variable with several levels), Shaffer argues that defining families becomes more complicated (and potentially more problematic) in large, more complex studies where alpha corrections can substantially lower statistical power (i.e., increase Type II error). To balance concerns about Type I and Type II error, a family will therefore be defined as the set of measures derived from a particular outcome assessment, and an alpha correction procedure will then be used (the unweighted Bonferroni) to control for error-rates within families. The resulting critical *p* values will be: FPI, 0.05/16 = 0.003; CFSQ, 0.05/3 = 0.017; FKQ, 0.05/6 = 0.008; compensation trials, 0.05/1 = 0.05; EAH, 0.05/1 = 0.05; FPQ, 0.05/2 = 0.025; CEBQ, 0.05/8 = 0.006; BMI, 0.05/2 = 0.025. Only results that meet these critical values will be reported in the primary analyses. To minimize the probability of Type II error, these critical values will be applied only to *p* values for the simple main effects analyses of time given the limited power of condition by time interactions in this type of design.[59]

Finally, exploratory analyses will be run on variables that show condition by time interactions in the pre-post analyses reported by Hughes and colleagues[45] but do not show significant interactions in the current study. Because the smaller samples at follow-up may reduce the power to find significant time by condition interactions at 6- and 12-months, simple main effects analyses of time were be run separately for the control and prevention groups to determine if the condition effects found in earlier pre-post analyses[16] persisted for the variables in the current study.

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