Research Methods

Strategies for Effective Eating Development—SEEDS: Design of an obesity prevention program to promote healthy food preferences and eating self-regulation in children from low-income families

Sheryl O. Hughes, Ph.D.¹, Thomas G. Power, Ph.D.², Ashley Beck², Drew Betz, Ph.D.², Shirley Calodich, MPH, RD.², L. Suzanne Goodell, Ph.D., RD³, Laura G. Hill, Ph.D.², Rachael Hill², J. Andrea Jaramillo¹, Susan L. Johnson, Ph.D.⁴, Jane Lanigan, Ph.D.², Adair Lawrence, M.S.², AnaMaria Diaz Martinez, MEd², Merrienneeta Nesbitt⁵, Irene Overath, Ph.D.², Louise Parker, Ph.D.², & Sarah Ullrich-French, Ph.D.⁶

¹ USDA/ARS Children's Nutrition Research Center, Department of Pediatrics, Baylor College of Medicine shughes@bcm.edu; andrea.jaramillo84@msn.com;

² Department of Human Development, Washington State University tompower@wsu.edu; aeaton@wsu.edu; betz@wsu.edu; sbroughton@wsu.edu; laurahill@wsu.edu; rachael.hill@live.com; janigan@vancouver.wsu.edu; roverath@wsu.edu; parker@wsu.edu; anamaria.martinez@wsu.edu; alawr@wsu.edu

³ Department of Food, Bioprocessing, and Nutritional Sciences, North Carolina State University, Raleigh, NC lsgoodel@ncsu.edu

⁴ Department of Pediatrics, Section of Nutrition, University of Colorado School of Medicine, Aurora, CO susan.johnson@ucdenver.edu

⁵ Office of the Provost, Washington State University mnesbit@wsu.edu

⁶ Department of Educational Leadership, Sport Studies, and Educational/Counseling Psychology,
Washington State University sullrich@wsu.edu

Corresponding Author: Sheryl O. Hughes, PhD, Associate Professor, Children's Nutrition
Research Center, Baylor College of Medicine, 1100 Bates Avenue, Houston, TX 77030-2600,
Phone: 713-798-7017, Fax: 713-798-0307, Email: shughes@bcm.edu

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ABSTRACT

Objective: To develop a scientifically-based childhood obesity prevention program supporting child eating self-regulation and taste preferences. This article describes the research methods for the Strategies for Effective Eating Development—SEEDS program. A logic model is provided which depicts a visual presentation of the activities that will be used to guide the development of the prevention program.

Design: Randomized, controlled prevention program, pretest, posttest, 6-months, 12- months.

Setting: Two sites – Houston, Texas and Pasco, Washington. Each trial will last 7 weeks with 8 to 10 mother-child dyads in each arm (prevention and control).

Participants: Recruitment at Head Start districts (Texas; n = 160) and Inspire Child Development Center including Early Childhood Education and Head Start (Washington; n = 160). Sixteen trials with 16-20 parent-child dyads per trial will provide adequate power to detect moderate effects.

Prevention Program: Multicomponent family-based prevention program incorporating a dialogue approach to adult learning and Self-Determination Theory.

Main Outcome Measures: Child assessments will include observed taste preferences, caloric compensation, and Eating in the Absence of Hunger. Parent assessments will include parent-reported feeding, feeding emotions, acculturation, child eating behaviors, child food preferences, and child dietary intake. Heights and weights will be measured on parent and child.

Analysis: A multi-level growth modeling analysis will be employed to consider the nested nature of the data: time points (Level 1) within families (Level 2) within trials (Level 3).

Keywords: childhood obesity, prevention program, family based, child eating self-regulation, food preferences.

INTRODUCTION

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.

Programs developed to prevent childhood obesity in school aged children have had moderate success and limited long term impact.⁵⁻⁷ This may be due to the age of the child given that the first five years are important in the development of child eating behaviors⁸ or the lack of inclusion of parents and other family members. 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. Studies have shown that preschoolers possess the ability to regulate energy intake during meals^{9,10} and across successive meals over 24-hours¹¹ by starting and stopping eating in response to internal cues of hunger and fullness. 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, mothers 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 was not hungry, providing inadequate exposure to novel foods, and serving excessive portion sizes, may have deterred children from attending to internal fullness cues. Individual differences in child eating self-regulation have also been linked to child weight.¹⁵⁻¹⁷ Eating in absence of hunger (EAH) was associated with higher child and adolescent weight¹⁸⁻²¹ 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 have shown how children come to prefer novel foods. When exposing young children to novel foods, an effect of the **exposure amount** on choice and liking was shown.^{25,26} It took 8 to 15 or more exposures for children to learn to prefer novel foods²⁵ with results being replicated in a social marketing study²⁷ 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 (12%) greater** 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 mothers served their preschool children for dinner (median = 565 kcal) was greater than the average kcal of food

mothers 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 have been 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 were also prevalent in the larger environment (food advertising, billboards, food arrangement in the grocery store) which may encourage food choices without reasoned awareness of the long term impact on childhood obesity.³⁶

Numerous programs have been developed, mostly in the school setting, to prevent obesity in children, of which some have had moderate success.^{6, 7} However, they may be 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 healthful 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 exist for preschoolers designed to

specifically address the needs of low-income, minority families.⁸

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, currently no prevention program addresses these issues in low-income families. SEEDS will incorporate a dialogue approach to adult learning³⁹ 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 parents and children is expected to increase program impact.

Although SEEDS will be developed for use with all low-income families, the first efficacy study will target low-income Hispanics because 1) Hispanics are at a high risk for childhood obesity, and 2) a homogeneous sample will help to better understand the impact in a single group before applying the program to additional groups. The study objectives will be:

- 1) to develop a scientifically-based, culturally relevant 7-week family-based obesity prevention program focused on supporting child eating self-regulation and exploration of novel foods; and
- 2) to test program efficacy by conducting a randomized controlled trial among Hispanic families with preschoolers at 2 separate locations. Children in the prevention program are expected to increase eating self-regulation, increase fruit and

vegetable intake and variety, and parents will increase responsive feeding behaviors.

METHODS

Study design

The SEEDS study will utilize a randomized controlled trial design to measure program efficacy. The study will be conducted at 2 sites – a large urban city (Houston, Texas) and a smaller agricultural community (Pasco, Washington). Each trial will include a prevention arm and a control arm lasting for 7 weeks; each arm will include 8 to 10 parent-child dyads. The prevention arm will receive the program curriculum consisting of a parent component with 7 lessons, a child component with 7 lessons, and a family component where the parent and child come together for a meal **with each of the 7 lessons**. The control arm will receive no curriculum but will last the same amount of time. Eight trials will be implemented at each of the 2 sites, yielding a total of 16 trials across the study. Identical assessments will be obtained on participants in the prevention arm and the control arm. Assessments will be administered 4 times – 2 to 3 weeks prior to the program, 2 to 3 weeks after the program, and at 6 and 12 months post program. This study was approved by the institutional review boards at Baylor College of Medicine and Washington State University.

Participant recruitment. The SEEDS study will target families known to be at high risk for child obesity rates—low-income Hispanic parents and their preschool children. In Houston, Texas, families will be recruited from Head Start districts in Harris County. In Pasco, Washington, families will be recruited from the Inspire Child Development Center—a network of inter-related programs including the Early Childhood Education and Assistance Program and Head Start. These comprehensive preschool programs provide free services and support to low-income families, **with the goal to** ensure all children enter kindergarten ready to succeed. By

recruiting and implementing in both states, a diverse group of Hispanic families will participate in the program evaluation, including families from agricultural communities and urban settings.

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 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.

Determination of Sample Size. The sample size was determined using Gpower 3.1.1⁴¹ considering 3 levels of clustering in the data: repeated measures (level 1) will be clustered within parent-child dyads (level 2), and parent-child dyads will be clustered within trials (level 3). Assuming a sample of 16-20 parent-child dyads for each trial (16 trials in total), a medium intra-class correlation of 0.15,⁴² a moderate correlation of 0.5 across time (4 measurement occasions), and an alpha of 0.05, there will be adequate power (80%) in the proposed analyses to detect a moderate effect size ($f = 0.25$) for all main effects and interactions.

Logic Model (Figure 1)

The logic model for this study provides an explicit and visual statement of the activities that will bring about change and the expected results. Acting as a road map, the logic model shows the steps to be taken to reach the outcomes and shows how the activities are linked to the results of the program. Additionally, each component of the logic model allows for evaluation to take place. Specifically, the logic model includes 3 core components: Inputs, Outputs (Activities and Participation), and Outcomes (Short, Medium, and Long Term)—a pictorial model of individuals and organizations that will provide input during different stages

(Inputs), the framework for how the prevention program will be developed (Outputs), and final results (Outcomes).

Hypotheses (Figure 2)

As shown in Figure 2, it is predicted that mothers who participate in the SEEDS intervention (i.e., through the parent and family sessions) will show more authoritative feeding styles, less directive feeding practices, and more positive emotions during feeding. These changes in feeding practices, as hypothesized by self-determination theory, will in turn yield greater child self-regulation of intake, child willingness to try new foods, and child preferences for fruits and vegetables. These same child outcomes will be influenced **directly by** children's participation in the child sessions. Finally, these changes in child eating practices will result in reduced child BMI at the follow-up time points.

Program Description

SEEDS will be a family based, culturally relevant, obesity prevention research program designed to promote healthful food preferences and self-regulation of eating in low-income families with preschoolers. Learning will be based on a dialogue approach to adult learning³⁹ and behavioral change will be based on Self-Determination Theory.⁴⁰ The dialogue approach³⁹ is consistent with principles of Self-Determination Theory that will facilitate deep learning of the program content. The dialogue approach is based on the following learning objectives: *anchoring* the content within the learner's experience, *adding* new information, inviting the learner to *apply* the new content to his/her own situation, and asking the learner to decide how or what information he/she will take *away* and use in the future.³⁹ Behavioral change in Self-Determination Theory is guided by the idea that the key to understanding self-regulation of human behavior is through examining environmental processes that nurture (versus impede) self-determined behavior.⁴⁰ The focus will be on developing intrinsic motivation and integrating

218 extrinsically motivated behaviors into autonomous, self-regulated behavior. Evidence
219 demonstrates that intrinsic motivation is promoted by providing choices, acknowledging
220 feelings, and providing opportunities for self-direction; self-determined motivation is
221 discouraged by expected tangible rewards, threats, demands, pressured evaluations, and imposed
222 goals.^{40,43}

223 Self-Determination Theory is supported by research on food preferences and the self-
224 regulation of energy intake. External pressure to engage children in healthful eating patterns
225 often has the opposite effect. Excessive pressure from adults to consume healthful foods (e.g.,
226 using food as a reward, forcing children to clean their plates, pressuring children to eat certain
227 foods) can lead to a *decreased* preference for healthful foods, and interfere with the process of
228 self-regulation involving sensitivity to internal fullness and hunger cues.^{44,45} Successful feeding
229 behaviors involve low levels of external pressure such as: 1) serving a variety of foods and
230 allowing the *child* decide how much to eat; 2) modeling consumption of healthful foods; 3)
231 involving the child in shopping for and preparing healthful foods; and 4) offering the child
232 choices within a set of healthful foods.⁴⁴

233 Coding of audio/videotapes of 80 families during dinnertime will provide a better
234 understanding of how maternal responses to child eating may override children's internal
235 fullness and hunger cues, thereby interfering with the effective self-regulation of energy intake.⁴⁶
236 Further information regarding this observational method can be found elsewhere.⁴⁷ Focus groups
237 with Head Start families will provide information regarding how mothers decide when their child
238 is full (determining fullness), how mothers decide how much to place on the child's plate
239 (portion sizes), and perceptions of the child not eating enough versus eating too much. Both of
240 these endeavors will be used to inform curriculum development.

Curriculum will be developed to include parent, child, and family components for use in a 7-week program. The format of the SEEDS program is modeled on a 7-week family-focused prevention program that has been highly successful, offered in many US states and internationally in many countries.⁴⁸ One family focused prevention study showed high retention rates with a 7-week program.⁴⁹ Modules will be developed by an interdisciplinary team from psychology, parent education, extension, nutrition, and early childhood development. The team will divide into smaller groups to develop individual lessons and then rejoin into the larger group to discuss and rework the lessons.

The parent component will be comprised of group experiential activities along with video-based instruction portraying common family scenarios. Twelve videos will be developed specifically to be interspersed throughout the lessons. Parents will view common scenarios, questions will be portrayed on the screen to facilitate parent discussion, and strategies will be provided to guide parents in managing similar situations at home. Individual goal setting will be incorporated with guided opportunities to apply program content. The 7 parent lessons will include: Introduction, Trying New Foods (how children develop preferences), Internal Cues of Hunger and Fullness (how children decide when they've had enough to eat; how parents know when their child has had enough to eat), Portion Size (how parents decide on appropriate portions for preschoolers), Structure of the Environment (outside influences), Structure of the Home Environment (structure of the home meal), and Review (responsive feeding). A more detailed description of the parent lessons is found in Table 1.

The child component will involve a series of activities focused on exploring and trying new foods and identifying internal cues of hunger and fullness (similar to the content in the parent lessons). The 7 child lessons will include book reading, child-centered play, and routines

based on early childhood education.⁵⁰ Colorful dolls with detachable Velcro stomachs will be used throughout the lessons to help children identify and describe their own cues of hunger and fullness. Novel foods will be introduced each week and children will be encouraged to explore these foods during the child lessons.

The family component will provide parents and children with an opportunity to share the concepts learned in individual lessons with each other. A meal will be provided for the parents and children at the beginning of each lesson; staff members will be included in the meals to encourage continued bonding with program participants.

The overall approach of the SEEDS program will be to create a culturally relevant intervention based on several core values including *familismo*, *respeto*, *educación*, and *simpatía*. With these values in mind, several practical steps will be taken in the delivery of the intervention. Bilingual interventionists will ensure intervention delivery is consistent with Hispanic cultural values. Despite many within-group differences,⁵¹ Hispanic cultures promote the value of collectivism which emphasizes the importance of the group before the individual.⁵² *Familismo* is a core value that includes the commitment to support family members and reliance on family for help.⁵² To respect *familismo* value, an emphasis is put on family health not individual health. *Respeto* (i.e., respect) is another core value that will be implemented throughout the program.^{53, 54} Research staff will convey information without disagreeing or challenging parents but rather by fostering and encouraging discussions. Research staff will provide information and allow parents the autonomy to decide how this information is used within the family environment. Providing the family with information is consistent with the value of *educación* (i.e., education)^{53, 55} which means more than simple transmission of knowledge. Research staff will open dialogues among the parents and foster an environment of

applying the lessons and strategies to the home environment. Another value to be promoted is *simpatia* or positive interactions among the parents and research staff,⁵² such as research staff joining the families during the meal at the beginning of the lessons and allowing all parents to express their concerns and ideas during the discussions. Additionally, family nutrition will be emphasized rather than nutrition for the individual. Research staff with expertise in Hispanic culture will assist parents with categorizing traditional foods, creating guidelines for reasonable serving sizes of traditional foods, and offering suggestions for ways to cook traditional foods healthfully.

Training for Program Facilitation Staff

Bilingual staff members will be hired to fill parent and child facilitation positions. To ensure facilitators have the knowledge and background to optimize behavior change integrated into the program, a degree in psychology or education will be required for parent facilitators and training or experience in early childhood education will be required for child facilitators. Staff hired for these positions will attend a 2-day intensive training session guided by the investigators who are developing the program. Hired staff will study the training manual to familiarize themselves with the program content. They will practice delivering lessons during the training session and guided to maximize participant engagement and involvement using parenting education principles. Once the trials begin, investigators will debrief the staff after each lesson by answering questions and providing feedback.

Data Collection

Data will be collected from preschool children and their parents at the child development centers where the trials will be implemented in Houston, Texas and Pasco, Washington. Assessment data will be collected before the trial begins (pre-assessment), after the 7 week

program ends (post-assessment), and at 6 and 12 months post program (follow-up). Assessments will occur over a 2 to 3 week period. For each assessment day, 8 staff will assist in data collection.

Training for 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 in psychology or nutrition (or similar degree) will be required. To ensure consistency in training, all assessment staff will attend a single intensive training session.

Assessment Methods

Overview. Assessments will be completed with the parent and the child. Parents will report on demographic including age, ethnicity, education, and employment status for descriptive information. Child assessments will include 2 eating self-regulation measures (caloric compensation and Eating in the Absence of Hunger) and an observational measure of taste preference. Parents will report on feeding, feeding emotions, and their child's eating behaviors and child food preferences. Acculturation information will be obtained from the parents. Height and weight will be measured on the parent and child. Outcome variables from each assessment are described in Table 2.

Child Eating Self-regulation Observations

Self-regulation of energy intake. Each child will participate in compensation trials to assess their self-regulation of energy intake according to the method developed by Johnson and Birch.¹⁵ On Day 1, each child will consume a high-energy or low-energy drink as a first course or preload. Thirty minutes later, each child will self-select a variety of foods and eat *ad libitum* (consume until no longer hungry). On Day 2, each child will receive the alternate version of the

preload, and consume a self-selected meal. Food intake will be measured by pre-weighing and post-weighing all foods. Energy intake of foods will be calculated using manufacturers' information as is standard practice in this field.^{14, 15} The index of child self-regulation or compensation, COMPX, is derived from the extent to which each child adjusts his/her *ad libitum* intake: children who are sensitive to the energy density of the drink will compensate by eating less at the meal after consuming a high-energy drink. The COMPX is a stable indicator of child self-regulation¹⁵ and has been used successfully in an intervention to improve young children's self-regulation of energy intake.⁵⁶

Eating in the Absence of Hunger. Eating beyond satiation will be measured on each child through a task developed by Fisher and Birch.⁵⁷ Prior to the task, each child will be provided with a complete meal based on 44% of the daily food requirements for a 4 to 5 year old child. Both sweet and savory snacks and age appropriate toys will be offered to each child. Each child will be left with the food and toys for 10 minutes and told they can eat whatever they want and play with whatever toys they like. Snacks remaining after the 10 minute period will be measured and kilocalories ingested will be determined. Scores on this task will reflect the total number of kilocalories eaten in the absence of hunger for each child.

Child Taste Preference Observation. A food tasting protocol will be administered to each child to assess his/her liking for foods and willingness to try new foods. In this protocol based on a procedure developed by Sullivan & Birch,⁵⁸ each child will be asked to taste 5 familiar and 4 novel foods in a self-selected order. The foods will represent a variety of food groups including foods to which children may have a neophobic response. Observers will record whether each child tastes the food or refuses it along with exploration of the foods (smelling, licking, spitting).

Parent Feeding and Emotions

Child Feeding Questionnaire. The Child Feeding Questionnaire (CFQ) is a parent-report measure of feeding attitudes and practices.⁵⁹ The CFQ has 4 attitude scales and 3 feeding practice scales. The latter will be used to measure feeding practices of the parent (restriction, monitoring, and pressure to eat). Twenty additional items developed by Johnson and colleagues⁶⁰ measure: promotion of autonomy, offering new foods, structure in feeding, and promoting internal control of eating. Confirmatory factor analyses show this measure is valid and reliable for use with Hispanic parents.⁶¹ Predictive validity of the CFQ has been demonstrated across multiple studies.⁶²

Caregiver's Feeding Styles Questionnaire. The Caregiver's Feeding Styles Questionnaire (CFSQ) is a parent-report questionnaire developed by Hughes and colleagues⁶³ to measure feeding styles of low-income parents. Parents indicate on 5-point scales how often they use 7 child-centered (e.g., reasoning, complimenting) and 12 parent-centered (e.g., demands, threats) feeding directives. Scores are derived on 2 parenting dimensions (demandingness and responsiveness) and parents are classified into 4 feeding styles (authoritarian, authoritative, indulgent, and uninvolved). Indulgent feeding on the CFSQ was associated with child obesity in 3 samples.⁶³⁻⁶⁵ Evidence of test-retest reliability, internal consistency, convergent and predictive validity has been demonstrated.⁶³

Feeding Emotions Scale. The Feeding Emotions Scale (FES) is a brief instrument consisting of 20 items that measures different feelings and emotions parents have while feeding their child.⁶⁶ Confirmatory factor analysis supported a 2-factor model with independent subscales of positive affect and negative affect. Convergent validity was demonstrated by associations with a measure of general adult emotions.⁶⁶ Predictive validity was demonstrated by showing mean differences in affect across parent feeding styles.⁶⁶ Scores indicate positive and negative parent

affect during feeding episodes with the child.

Parent-report of Child Eating Behaviors. The Child Eating Behavior Questionnaire is a parent-report measure assessing 8 dimensions of eating in young children.⁶⁷ Validity and reliability have been demonstrated.⁶⁷ Three of the 8 subscales measure parent-report of child eating self-regulation (food responsiveness, enjoyment of food, and satiety responsiveness). To our knowledge, this is the only parent-report measure of satiety responsiveness in young children (responsiveness to fullness cues).

Parent-report of Child Food Preferences and Intake

Food Preferences Questionnaire. The food preference questionnaire used for this study was adapted from Skinner and colleagues.²⁹ This parent-report measure includes 112 food and drink items regarding their child's preferences using 3 categories: never tried, tried – like 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

Block Kids Food Screener. The Block Kids Food Screener is a food frequency questionnaire designed to measure parent-report of child intake (ages 2 – 17). This screener assesses child intake by food group consumed in the past 7 days (number of servings and caloric intake).^{68, 69}

Acculturation. The Bidimensional Acculturation Scale (BAS) consists of 3 subscales: language-use, language proficiency, and electronic media. The BAS is considered the best acculturation measure with the greatest validity.⁷⁰ The 3 subscales will be combined to create a Hispanic domain and a non-Hispanic domain. Evidence of validity and reliability has been shown in US samples.⁷¹

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).⁷² 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 underweight (< 5th percentile), healthy weight (5th to < 85th percentile), overweight (85th to < 95th percentile), obese ($\geq$ 95th percentile) according to Centers for Disease Control standards. BMI scores will be calculated for the parent in addition to being classified as low and normal weight (BMI<24.9), overweight (BMI>25) or obese (BMI>30).

Program Fidelity

Separate bilingual staff will be hired to conduct process evaluations on the parent and child lessons. For one-fourth of the lessons, a trained observer will be present to assess program fidelity through process evaluations. The trained observer will observe the lesson, complete a form which lists all lesson activities and content, and indicate whether all components of the lesson were delivered. Percent coverage scores will be calculated from these forms for each session. These observations will be conducted for the parent, child, and family sessions. Session facilitators will also note on any issues that arise during the sessions and these will be examined as part of the process evaluations.

Statistical Plan

Code books will be created for all variables. Any data entered by hand will be entered twice and reviewed to minimize data entry errors. Field and range checks will be conducted. Descriptive statistics including means, standard deviations, skewness, and kurtosis will be calculated to describe the basic features in the data set. Transformation to normality will be considered as appropriate.

Longitudinal analysis models will allow all available data to be used.⁷³ This strategy will be more efficient because partial information will be available for those participants who drop out. A likelihood ratio test based on pretest and posttest assessment information will determine whether dropouts occurred at random.⁷⁴ Primary comparative analyses will be conducted using intention-to-treat principles emphasizing confidence intervals for between group comparisons. Regardless of whether the complete prevention program was received, all eligible participants in the prevention group will be used to evaluate the program effects.

Outcome analyses will be conducted using multi-level growth modeling with residual maximum likelihood estimation and a (co)variance matrix approach^{75,76} to account for the nested data structure: time points (Level 1) within families (Level 2) within trials (Level 3). This approach enables program-related effects to be controlled (implementation quality) so standard errors and, therefore, program outcomes can be estimated more accurately despite the interdependence of observations within programs. It also allows for examination of variance within individuals within the same program separately from changes across programs, and variance related to initial values on outcomes measures (e.g., starting BMI). Random effects will include: time, participant, and program; fixed effects at the individual level will include demographics, acculturation, dosage (program attendance), and starting values on parents' feeding styles and knowledge (and children's BMI for BMI outcome analyses); fixed effects at the program level will include implementation quality indices. To inform the selection of covariates in further analyses, a bivariate analysis will be conducted on independent and dependent variables at baseline.

Additionally, dose received will be assessed by employing process evaluation measures during the implementation of the prevention program. Simple descriptive statistics will be used

(i.e., frequencies) employing class attendance records to report the number of classes each participant attends and retention of the participants to the prevention program to describe how activities are received by the participants. All analyses will be conducted using SAS version 9.4 (SAS Institute, Cary, NC)

DISCUSSION

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 child self-regulation of eating, the exploration of novel foods, and the role parents play in the socialization of these child eating behaviors.⁸ The SEEDS program will be one such prevention program.

Consistent with Self-Determination Theory, parents who most effectively encourage the development of healthful eating behaviors such as healthful food preferences and eating self-regulation use child-centered feeding directives, acknowledge child feelings, and afford child opportunities for self-direction. In contrast, parents who interfere with healthful preferences and self-regulation rely on counter-productive strategies such as tangible rewards, threats, demands, and pressured eating.

Parents in the SEEDS prevention group are expected to: 1) use more child-centered and less parent-centered feeding directives, 2) be less likely to show an indulgent and more likely to show an authoritative feeding style, 3) show lower scores on restriction and pressure to eat and higher scores on monitoring, and 4) report higher levels of positive and lower levels of negative feeding emotions. Children in the prevention group are expected to show: 1) more willingness to try new foods, and 2) increased self-regulation of energy intake. At the end of the prevention program, both parents and children (especially children) are expected to show greater

consumption of fruit and vegetables (including consuming a wider variety of these foods). All effects are expected to continue through the 6- and 12-month assessment periods, although the effect sizes will diminish. Effects on child weight status are not expected at posttest, but decreases in children's BMI percentiles by the 6- and 12-month post prevention periods for the prevention group are expected— especially for the top 25% of the BMI percentile range. No changes in parent weight status are expected.

Challenges to the program effectiveness will include our ability to recruit and maintain program participation. Parent time demands and work obligations may interfere with program attendance and lack of transportation may limit participation. Parents may have difficulty implementing some of the parenting/feeding practices in their homes due to limited income and access to healthful foods. Children may not respond positively to changes in parenting and feeding such as setting appropriate boundaries and limits. Other family members such as spouses may not support attempts to create a healthier home environment. Multiple steps will be taken by program staff to help parents and children implement behavioral changes supported by this prevention effort.

Steps to address these challenges include having study staff complete extensive training and certification prior to implementing the efficacy trial, having parent facilitators implement numerous brainstorming sessions during the lessons to help families implement and maintain behavioral changes in their own environment, obtaining various forms of contact information from each family, and maintaining contact with families between lessons and assessments to help with retention of the sample. Key strengths will include the multi-disciplinary approach to program development, the proposed use of Self-Determination Theory to inform behavioral change, the randomized control nature of the design, the use of observational measures for

493 assessment of the children, and the potential ability to provide insights into obesity prevention
494 effects in this homogenous high risk population. Ultimately, the SEEDS study will have the
495 potential to help decrease the risk for childhood obesity in Hispanic families and possibly other
496 low-income groups after conducting further formative assessment, program modifications, and
497 summative evaluation with those groups.

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Figure Legends

Figure 1. The logic model includes 3 core components: Inputs, Outputs (Activities and Participation), and Outcomes (Short, Medium, and Long Term).

Figure 2. Conceptual Model.

Table 1

Table 1. Description of parent lessons to be developed

<i>Lessons</i>	<i>Content</i>	<i>Learning Objectives</i>	<i>Anchor</i>	<i>Add</i>	<i>Apply</i>	<i>Away</i>
<i>Lesson 1 Introduction</i>	<ol style="list-style-type: none">1. Getting acquainted2. Introduce SEEDS program and food goals for child3. Set goal for a new family food experience		Parents will discuss things they are trying to achieve when feeding their children.	Play Video #1 and Video # 2. These videos will cover the introduction and goals of the SEEDS program.	Activity about identifying family mealtime scenarios. Parents will select a photo that is similar to a meal in their own home.	Parents will discuss things to try at home. Staff will distribute SEEDS magnets.
<i>Lesson 2 Trying New Foods</i>	<ol style="list-style-type: none">1. Child may taste food 8-12 times before accepting2. Exploring can help a child become familiar and accept new food3. Preparing food in different ways may help with liking	<ol style="list-style-type: none">1. The number of times to introduce new foods to children2. Better understand the process children undergo to learn to like new foods3. Strategies for creating a family plan for new food experiences4. How to introduce a new food at home	Play Video #3 (What’s That?). Discuss children’s reactions to trying new foods.	Play Video #4 (How Many Times Does it Take?) and Video #5 (Introducing New Foods). Parents will discuss exposure to new foods and the number of times it takes for acceptance. Parents will discuss how introducing new foods can be a struggle.	Parents will brainstorm ways to introduce new foods. Will use a flip chart with headings of Strategies (on one page) and Possible Solutions (on another). Tasting activity for parents (hummus and garbanzo beans).	Staff will distribute ‘Things to Try at Home’ cards. Parents will be encouraged to try new foods at home.
<i>Lesson 3 Internal Cues of Hunger and Fullness</i>	<ol style="list-style-type: none">1. Children can learn to recognize hunger and fullness cues2. Children can respond to cues and communicate this to parents3. Adults and children have different roles at meals.	<ol style="list-style-type: none">1. Better understand feelings of hunger and fullness2. To pay attention to internal cues and how this facilitates healthy eating3. What causes children to ignore or follow their own cues4. Parent and child roles at mealtimes.5. What makes it hard for parents to trust child cues	Parents will discuss hunger and fullness cues. Parents will describe how it felt when they waited longer than usual to eat, when they ate more than usual, and when they ate the appropriate amount.	Play Video #6 (Listening to our Cues) and have parents discuss scenarios from video. Play Video #7 (Parent and Child Roles) and have parents discuss roles during eating episodes.	Activity with statements describing different mealtime roles. Parent will identify whose role it is (parent or child).	Staff will distribute tool developed for children to let their parents know they are full. Staff will remind parents that the child’s role is to decide if and how much to eat and suggest talking to their child about fullness cues at home. Staff will distribute card (handout) on parent and child roles at mealtimes.
<i>Lesson 4 Portion Sizes</i>	<ol style="list-style-type: none">1. Children’s stomachs are about the size of their fists.	<ol style="list-style-type: none">1. Appropriate portion sizes for preschoolers.2. Experience measuring	Parents will discuss what they think about or consider when	Play Video #8 (Child Portions). Parents will discuss how much	Activity for parents to practice serving child sized portions using	Staff will distribute handout related to portion sizes. Staff will

	<ol style="list-style-type: none"> As a guide, child portions are about one tablespoon per year of the child's life. 	<ol style="list-style-type: none"> and comparing portion sizes for adults and children. Strategies to help children self-serve How to set up portion size goals for the home. 	deciding how much food to be placed on their child's plate. Staff will write responses on a flip chart.	children actually need to eat.	measuring spoons and cups and normal size serving spoons on standard and child sized plates. Compare a child sized snack bag to an appropriate child size serving (3-5 yrs).	distribute a child-size cup, a tablespoon, and a ¼ measuring cup for each parent to use to serve the child or allow the child to serve him/herself at home. Encourage parents to be aware and practice appropriate portion sizes during mealtimes.
<i>Lesson 5 Structure of the Environment (Outside Influences)</i>	<ol style="list-style-type: none"> Plan shopping trips. Grocery and convenience stores are arranged to increase spending on specific kinds of foods—healthy and unhealthy. The freshest and healthiest foods are usually in the outside grocery store aisles. Grocery stores intentionally market/advertise to children. Food is placed on shelves at the right height to catch the child's eye. Tempting treats are places near the cash register to catch attention when waiting in line. 	<ol style="list-style-type: none"> Awareness of cues in the environment that influence eating Strategies to deal with environmental cues to eat when away from home 	Parents will discuss messages and cues in the environment when walking or driving down the street. Parents will discuss some of the cues that are tempting when hungry.	Play Video #9 (Cues to Eat: On the Street). Parents will discuss what they saw in the video such as cues to eat, foods and quantity being encouraged .	Play Video#10 (Grocery Store and Drive-through Scenes). Discussion questions to be embedded in the video after each scenario. Video will be paused at these places so parents can discuss.	Staff will distribute handout on planning, arrangement of items in grocery stores, and marketing to children. Staff will distribute handout related to eating better on a budget.
<i>Lesson 6 Structure of the Home Environment</i>	<ol style="list-style-type: none"> Mealtime routines help children learn about the world and feel secure. Mealtime routines can help a child eat better. Meals for young children should last between 15-20 minutes. 	<ol style="list-style-type: none"> How to set up healthy eating routines at home. Strategies for creating routines that work in the family. 	Children learn about the world from patterns and repetition which help them understand their place in the world and in the family. Discuss some daily routines and eating routines in the families of participants.	Play Video #11 (Mealtime Routines). Video will be paused after mealtime scenarios and questions will appear on the screen. Parents will discuss mealtime scenarios and their importance for young children.	Parents <i>will</i> divide into groups of 3 and brainstorm solutions to difficulties in establishing home routines.	Staff will distribute handouts about how to establish mealtime routines in homes. Staff will distribute handout regarding strategies for being a healthy role model for children.

<i>Lesson 7 Review</i>	1. Review of 7 lessons	1. Successes and challenges in achieving program content 2. Review of responsive feeding 3. Graduation	Play Video #12 (Let's Review). Parents will discuss what was learned in the SEEDS program and strategies and barriers to implementing what was learned			Staff will dismiss parents for graduation.

Table 2. Assessments and variables to be derived for analysis from assessments

<i>Construct</i>	<i>Assessment Tool</i>	<i>Type of Administration</i>	<i>Target</i>	<i>Variables to be Derived</i>
Sensitivity to cues of hunger and fullness	Caloric compensation trial (Johnson & Birch, 1994)	Observation	Child	Self-regulation of energy intake (sensitivity to energy content of foods eaten)
Eating beyond satiation	Eating in the Absence of Hunger (Fisher & Birch, 1999)	Observation	Child	Total number of calories eaten in the absence of hunger
Taste Preference	Food tasting protocol (Sullivan & Birch, 1990)	Observation	Child	Willingness to try new foods
Feeding practices	Child Feeding Questionnaire (Birch et al., 2001)	Self-report	Parent	Restriction; Monitoring; Pressure to eat; Promotion of autonomy; Offering new foods; Structure in feeding; Promoting internal control of eating
Feeding styles	Caregiver's Feeding Styles Questionnaire (Hughes et al., 2005)	Self-report	Parent	Authoritative, authoritarian, indulgent, uninvolved feeding styles; parent- and child-centered feeding
Feeding emotions	Feeding Emotions Scale (Frankel et al., 2015)	Self-report	Parent	Positive and negative parent emotions during feeding
Child eating behaviors	Child Eating Behavior Questionnaire (Wardle et al., 2001)	Parent-report	Child	Satiety responsiveness; Food responsiveness; Enjoyment of food
Food preferences	Food Preferences Questionnaire (Skinner et al., 2002)	Parent-report	Child	Child fruit and vegetable preference
Food intake	Block Kids Food Screener (Block & Naughton, 1990)	Parent-report	Child	Child intake by food group (# of servings; caloric intake)

Acculturation	Bidimensional Acculturation Scale (BAS; Marin et al., 1996)	Self-report	Parent	Parent acculturation into the US culture
Anthropometrics	Height and weight	Observation	Parent; child	BMI, weight categories of normal, overweight, obese

Figure

Figure 1. Logic Model

Figure 2. Conceptual Model

CFQ: Child Feeding Questionnaire; CFSQ: Caregiver's Feeding Styles Questionnaire; FES: Feeding Emotions Scale; CEQB: Children's Eating Behavior Questionnaire