

## Study Protocol

Official Title: Family Empowerment for Enhanced  
Development (Project FEED)

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**Scientific Background:** Despite increased public awareness, childhood obesity rates have nearly tripled over the past four decades and remain high. Child onset obesity takes a toll on all aspects of health, as it increases risk for poor school performance, social isolation, Type 2 diabetes, sleep apnea and predicts obesity as an adult. Low-income preschoolers are disproportionately affected; approximately 15% of preschoolers from low-income families are obese prior to their fifth birthday, as compared with 8% observed in the general population. Building preventative healthy habits during early childhood is crucial, as rates of obesity increase among school-age children. While it is clear that genetics and social factors, such as income, ethnicity, and minority status, influence obesity, poor nutrition and lack of physical activity are recognized as the primary causal mechanisms. Therefore, the World Health Organization has called for interventions to improve nutrition and physical activity early in life. Specific to building healthy dietary variety, early intervention is vital because children are more receptive to trying new foods prior to age five, and early food preferences in young children are likely to carry forward into adulthood. Partnering with families to build healthy dietary habits early is a pivotal component of obesity prevention efforts. Our study will focus on this outcome, promoting healthy nutrition, among low-income preschoolers.

Because parents are responsible for the timing, setting, and foods offered during child meals, they hold the key to shifting the mealtime routines of young children. Embedding parent-mediated intervention strategies into a child's daily natural environment has been widely endorsed as best practice, yet evidence to support current methods of parent-training in the home is limited. Innovative parent-training strategies are needed, as parents of young children report difficulty incorporating new skills into established daily routines. Our pilot data support the premise that training parents to create a mealtime environment enriched with healthy role models and repeated exposure to a variety of foods can improve child nutrition. We predict that these behavioral and environmental changes are more likely to persist when routines are family-centered and practiced in the natural environment.

Motivational interviewing and anticipatory guidance have been used to change home routines of preschoolers. While these techniques have improved routines related to sleep and television watching, changes in mealtime have not been observed and effects on child nutrition are unclear. Many of these studies offer disparate strategies to support healthy weight management without connecting these strategies to existing family routines or considering unique family dynamics. These strategies can be modified to meet the needs of each family, but this opportunity is often overlooked. This is particularly important for low-income parents who are likely to be focused on surviving life stressors, and have limited resources to independently solve these problems. Additionally, these interventions are delivered in a variety of formats (face-to-face, mail, phone calls, text messages), some of which lack the capacity for individualized problem solving to overcome barriers. While parents perceive mailed and phone-based intervention-delivery as convenient, they may lack the structure and support required for long-term behavior change.

Furthermore, few studies include formal follow-up procedures related to successes and failures implementing new routines or strategies. Our prior research highlights the importance of individualized feedback during routine family activities. In a small pilot trial of the Mealtime PREP intervention, we found that those children whose parents received feedback during actual family meals were significantly more likely to respond to treatment than those who had received feedback based on parent report. Occupational therapists are uniquely trained to examine the dynamic transaction between the person (family), environment, and activity that they are engaged in to provide customized feedback or recommendations to support optimal performance. Evaluation of this dynamic interplay is lacking in current health promotion interventions of early childhood; the Mealtime PREP intervention provides a systematic

framework to deliver this feedback.

In our early pilot work, the Mealtime PREP intervention empowered parents from middle to high-income families to increase the frequency of family meals, feel confident about managing daily meals, and change daily mealtime routines. However, this study focused on children with Sensory Food Aversions and our convenience sample was homogenous and lacked diversity. Because of the complex barriers faced by low-income families, further investigation is required to determine how to best serve these families. Despite economic, attitudinal and accessibility limitations, longitudinal surveillance of this population has revealed that positive parenting interventions to prevent behavioral issues and aggression appear to have a protective capacity against obesity. While not the primary intent of these interventions, this evidence provides a signal that early intervention focused on parent education, empowerment, and behavior change is a promising approach for obesity prevention. While we are not able to test whether the Mealtime PREP intervention effectively prevents obesity over a 12-week period, the purpose of this trial is to gather data to optimize our approach and meet the needs of low-income families for future trials with long-term follow-up.

**Study Objectives:** The purpose of this pilot project is to trial the Mealtime PREP intervention program with a sample of low-income families.

Specifically, we aim:

1. To examine the feasibility and acceptability of the Mealtime PREP intervention among low-income families with a preschooler.
2. To estimate the effects of Mealtime PREP on dietary variety, nutrition, and mealtime behaviors of low-income preschoolers.

**Study Design& Methods:** We plan to use a prospective, repeated-measures study design with data collection occurring at baseline, 6 weeks (post-intervention), and 12 weeks (follow-up). Twenty low-income families with a preschooler will be recruited from waiting rooms and/or staff referral at local WIC, Head Start, and pediatric primary care offices. Interested parents will undergo basic screening procedures (i.e. providing responses to screening questions to determine eligibility) prior to being consented to participate in the study.

After eligibility has been confirmed, interested parent participants will undergo the consent process with a trained research assistant and/or the principal investigator in the home environment or an agreed upon alternative in the community. Following informed consent, baseline assessments (including video-recording a typical child meal) will take place. If the child meal is of average length (approximately 20 minutes), this session will last approximately 60-90 minutes. Additionally, they will be asked to complete a 3 day food diary where they log their child's food intake for three days.

Trained research interventionists will then schedule six weekly sessions to take place in the family home or an agreed upon alternative in the community. Each session will last approximately one-hour and will include didactic and practice portions with the therapist demonstrating techniques during a child meal and providing feedback as needed. The entire session will be video-recorded by the interventionist.

Mealtime PREP – Parent Experience: Parents are trained to deliver each intervention component during mealtimes using a step-wise, behavioral activation approach. The parent-

training prong of the Mealtime PREP intervention incorporates four active ingredients of behavioral activation (1. skills training; 2. goal-setting; 3. activity scheduling; and 4. activity monitoring) to help parents build a family meal routine that is enriched with techniques to promote child nutrition (Figure 1). Trained research interventionists with experience in pediatric occupational therapy will lead six weekly parent-training sessions in the home. During each session a new intervention component (e.g. Family Meals, Positive Reinforcement) to promote healthy child feeding habits will be introduced and parents will be provided direct feedback while practicing new skills during a child meal. Parents will work with the therapist to set-up a plan and set a goal to practice delivering intervention components in the home between parent-training sessions.

**Mealtime PREP – Child Experience:** The child-focused prong of the Mealtime PREP intervention embeds positive reinforcement of healthy eating habits and repeated exposure to targeted healthy foods into a consistent family meal routine. Parents will incorporate intervention components (Family Meals, Positive Reinforcement, Food Exploration and Food Play) into the child's routine sequentially, as they are trained to deliver them. In essence, the parent will provide a predictable family meal routine, encourage active child participation, reward healthy eating habits and redirect unhealthy behaviors to acceptable alternatives. Parents will also model healthy eating habits and demonstrate various ways to learn about healthy foods using exploration and play. The intervention will be customized to accommodate a variety of environments, address unique family barriers and incorporate child-centered play.

Trained research assistants and/or the principal investigator will conduct follow-up assessments within two weeks of intervention completion and approximately 12 weeks following baseline. Each assessment session is predicted to last approximately 60-90 minutes. They will also be provided with a 3-Day Food Diary and Self-addressed envelope at each of these sessions.

Primary outcomes include:

3-Day Food Diary (Caregiver Reported) Child Intake and Variety of Healthy Foods Preferred method of dietary assessment because of a balance between validity and burden. Includes all food consumed and approximate servings for 3 days.

NutriSTEP and NutriSTEP Toddler Child Risk of Nutritional Deficiency 17 item, validated screen for young children (1–5 years) that categorizes risk of nutritional deficiency into 3 categories (low, moderate, and high).

Parenting Stress Inventory-Short Form Parental Stress Validated tool to assess and categorize parental stress.

**Eligibility Criteria:** Families will be eligible for participation if they have a child in the age range of two to five years old and reside in a low-income household (as specified by income within the range to qualify for WIC services). Parent participants will be eligible for participation if they are > 18 years old, speak English, read at a 6th grade level, and agree to deliver intervention during daily meals.

## Statistical Considerations

**Data Analysis:** Specific Aim 1: To examine the feasibility and acceptability of the Mealtime PREP intervention among low-income families, we will rely on descriptive statistics (raw scores, frequencies, and percentages) to determine if each benchmark of feasibility has been met. Specific Aim 2: To estimate the effects (child dietary variety, nutrition risk, parental stress) of the

Mealttime PREP intervention, we will calculate effect sizes (Cohen's  $d$ ) based on mean scores of the sample at each time point. Effect sizes will be used to predict effects among low-income families and calculate appropriate sample sizes for future studies. For each outcome of interest, we will run exploratory paired t-tests ( $\alpha = .05$ ) using IBM SPSS Statistics, Version 24. If the data is not normally distributed or if there are outliers upon data exploration, we will switch to equivalent non-parametric tests (e.g. Wilcoxon Signed-Rank). These results will serve as a signal of the ability of this intervention to change behavior over time.