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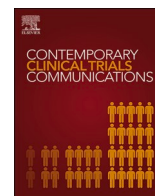
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Rationale, design and study protocol of the ‘Strong Families Start at Home’ feasibility trial to improve the diet quality of low-income, ethnically diverse children by helping parents improve their feeding and food preparation practices

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ARTICLE INFO

Keywords:

Feeding practices
Eating behavior
Nutrition
Preschool-aged

ABSTRACT

There is an urgent need to create effective interventions that help parents establish a healthy diet among their children early in life, especially among low-income and ethnically and racially diverse families. U.S. children eat too few fruits, vegetables and whole grains, and too many energy dense foods, dietary behaviors associated with increased morbidity from chronic diseases. Parents play a key role in shaping children’s diets. Best practices suggest that parents should involve children in food preparation, and offer, encourage and model eating a variety of healthy foods. In addition, while parents help to shape food preferences, not all children respond in the same way. Certain child appetitive traits, such as satiety responsiveness (sensitivity to internal satiety signals), food responsiveness (sensitivity to external food cues), and food fussiness may help explain some of these differences. Prior interventions to improve the diet of preschool children have not used a holistic approach that targets the home food environment, by focusing on food quality, food preparation, and positive feeding practices while also acknowledging a child’s appetitive traits. This manuscript describes the rationale and design for a 6-month pilot randomized controlled trial, Strong Families Start at Home, that randomizes parents and their 2-to 5-year old children to either a home-based environmental dietary intervention or an attention-control group. The primary aim of the study is to explore the feasibility and acceptability of the intervention and evaluation and to determine the intervention’s preliminary efficacy on child diet quality, feeding practices, and availability of healthy foods in the home.

1. Background

Suboptimal diet is the leading risk factor for death and disability in the US [1,2]. The diet quality of US children is poor, with too few fruits and vegetables and whole grains, and over-consumption of energy-dense snacks and beverages [3–6], especially among low-income ethnic and racial minorities [7,8]. Unfortunately, this dietary pattern is associated

with increases in markers of chronic disease risk in young children [9–13] and contributes to chronic disease risk in adults [14–17]. The preschool years are a critical time for shaping food preferences which track into adulthood [18–38]. Thus, there is an urgent need to improve diet quality especially among low-income and ethnic/racial minority children.

Parents play an important role in shaping children’s dietary

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<https://doi.org/10.1016/j.conctc.2020.100583>

Received 3 February 2020; Received in revised form 18 May 2020; Accepted 7 June 2020

Available online 16 June 2020

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preferences. [39–43]The consumption of foods outside the home [44–46], unhealthy foods available in the home [47,48], and lack of home-prepared meals [49–51], are related to suboptimal child diet quality. One area where parents want guidance [52,53] is with child interactions during mealtimes, commonly known as food parenting practices. Food parenting practices (such as involving children in meal planning/preparation, making healthy foods available, and healthy modeling) are positively associated with children's diet quality [54–57]. In contrast, some food parenting practices hinder the development of healthy eating behaviors (including pressuring children to eat regardless of their hunger and satiety cues, and using food as a threat or bribe), which may undermine children's ability to self-regulate intake [56–61]. Interventions focused on food parenting practices typically address what parents should not be doing, instead of supporting what they should be doing [62]. Furthermore, interventions have not recognized that children respond to their food environments in different ways. Thus, interventions are needed to highlight what parents are doing well and focus on what tailored positive feeding practices they can incorporate into their mealtimes. Group and clinic-based approaches that promote positive practices such as repeated exposure of new foods, offering guided choice, modelling healthy behaviors, and offering a variety of healthful foods have achieved some success in modifying children's diet and/or body mass index (BMI) when parents regularly attended however attendance is generally low [63–68] and effects are short-lived [69].

Previous interventions have had limited success in reaching parents, keeping them engaged, and changing their child's behaviors [63,64,67, 70–72]. Interventions where parents have to travel to a location pose considerable burdens on low-income families, including the need for transportation and childcare [73,74]. There are challenges engaging and retaining busy, low-income ethnically diverse families [63,64,67,68,75, 76]. Thus, there is a clear need for novel interventions to reach busy parents.

One promising approach is to deliver interventions in the home. A recent review on healthy eating interventions highlights the need for such interventions, especially those theoretically driven and with consistent approaches to measurement and clarity regarding desired outcomes [77]. Few studies have used a theoretical framework to understand how to improve food-parenting practices and child diet quality [78].

This paper describes the development, implementation, and evaluation plans for *Strong Families Start at Home*, a home-based pilot intervention with low-income, ethnically and racially diverse families that aims to help parents identify and implement positive feeding practices, tailor their feeding practices to their child's unique needs, and utilize healthy food shopping and preparation strategies.

2. Methods

2.1. Study objectives

The study's objectives are threefold: 1) Determine the feasibility and acceptability of the intervention, 2) Determine the preliminary efficacy of the intervention on changes in children's diet quality (primary outcome), parental feeding practices and availability of healthy foods in the home (secondary outcomes), and 3) Calculate effect sizes for a future randomized controlled trial (RCT). This 6-month pilot RCT, which began in July 2019, randomly assigns parent-child dyads into one of two groups: the intervention group focuses on healthy feeding and the attention control group focuses on reading readiness. The study has been approved by the University of Rhode Island Institutional Review Board (HU1819-007) and is registered with clinicaltrials.gov (Trial NCT03923491).

3. Strong Families Start at home intervention development

3.1. Formative work

As part of a pre-pilot study, we recruited low-income mother-child dyads (N = 15, 87% White) from Women Infants and Children (WIC) clinics in Rhode Island to participate in a non-experimental 6-week, pretest–posttest pilot intervention study [79]. Following the short two home-based visit intervention, which included motivational interviewing (MI) feedback on an evening meal video-recording, mothers reported a decrease in the use of controlling food parenting practices, 'pressure to eat' (3.3 vs. 2.8, $p = .67$) and 'food as a reward' (2.3 vs. 1.7, $p = .03$). Mothers also reported an increase in the use of supportive food parenting practices, 'involvement' (3.0 vs. 4.0, $p = .08$), 'environment' (4.0 vs. 4.3, $p = .06$) and 'modeling' (4.3 vs. 4.8, $p = .12$). At the study's end, 93% of mothers 'strongly agreed' that it was worth their effort to participate and all mothers agreed 'strongly' (60.0%) or 'somewhat' (40.0%) that this home-based intervention increased their interest in learning to feed their child in healthy ways. Several mothers indicated that they liked watching the meal video-recording and none of the mothers felt embarrassed or upset as a result of the recording. One mother said, "Seeing the video and how I reacted was eye-opening. I liked getting information that I can apply to my own life and talking about what might work for my family." We also learned from mothers that they often have mixed feelings about introducing new foods to children multiple times because they feel that is wasting food. Similarly, it was also apparent that very few fruits and vegetables were being served to children. In addition, mothers reported feeling frustrated about the suggested strategies they received to get their child to eat because often it did not work for them. The most common complaint was because their child was a fussy eater. Thus, we determined that parents need tailored, not generic advice. We also learned that the use of the video-recorder to collect the videos was somewhat cumbersome as the research assistant had to place it before the meal and then return to the home after the meal. Thus, we decided that using parental smart-phones to video-record the meal instead of research staff would be more convenient and realistic, and could easily be scaled-up given that smart-phones are so widely used across income groups [80].

To further develop the intervention, we recruited parents from childcare centers and conducted five focus groups with 33 parents (three Spanish and two English language groups). Participants were primarily female (88%), Hispanic/Latinx (85%), and born outside of the US (69%). One third of participants were food insecure, measured using a two-item screener [81]. We asked parents about mealtimes in their homes and strategies they used to feed their children. Consistent with previous studies, parents reported having busy schedules and that feeding their young children can be challenging [82,83]. Parents reported that their primary concern was for their children to eat enough food, regardless of the type of food. Given the largely Hispanic population, many of them felt that culturally significant foods were important. Many parents reported frequent preparation of home cooked meals and a desire to model healthy eating for their children. However, families discussed struggling to get their children to eat the same meals as the family and often allowed their child independence in choosing what they ate at meals (often foods such as sweet cereals, juice, french fries, chicken nuggets). Many participants believed that it was often easier to let their children decide what meals to eat rather than having to struggle to convince children to eat.

We also asked parents their opinions on the different components of the planned intervention including home visits, text messaging, hand-outs and in-home cooking sessions. Overall, parents were receptive to the idea of someone coming into their home and in fact said that it would make it easier for them. Participants expressed mixed feelings when discussing the idea of the video-feedback. While the majority of participants felt that the video would provide valuable and useful information, some were concerned about being embarrassed with the videos

or that other family members may not like the idea of being recorded. Parents did not want to be sent more than two text messages per week as they felt like they were already getting too much information. They also reported a desire for a forum to communicate and connect with other parents.

3.2. Community advisory board

A community advisory board (CAB) was convened during the first year of the grant and includes leadership from the Rhode Island’s Special Supplemental program for Women Infants and Children, the Supplemental Nutrition Assistance Program Education, Rhode Island Department of Health, YMCA, KidsCount, Ready to Learn Providence, and Providence Community Health Centers (local organizations that work with children in Rhode Island). The CAB meets quarterly and has advised on the refinement of the materials and protocols, intervention and evaluation tools. They are also assisting with recruitment and intervention implementation, as well as the interpretation and dissemination of study findings.

Based on previous literature, our formative work, suggestions from the CAB, a review of the literature on improving diet quality in preschool aged children, we used the intervention mapping approach [84] to design the intervention. First, we defined program and performance objectives (see Supplementary Tables 1 and 2) to ensure that the developed intervention would guide participants towards improvements in child diet quality, food parenting practices, and the home food environment [85–87]. Examples of performance objectives include but were not limited to: parents will increase availability of fruits, vegetables, whole grains, lean protein, and low fat dairy in the home; parents will involve children in meal preparation; parents will role model healthy eating; and, parents will provide opportunities for repeated taste exposure of healthy foods (i.e. vegetables).

3.3. Intervention overview

The 6-month pilot intervention, delivered in both English and Spanish, consists of two parts. During the first 3 months, parents receive monthly home visits by a community health worker (CHW) trained in motivational interviewing (MI) and text-messages two times per week. For the remaining 3 months of the intervention, parents receive monthly mailed materials, text-messages twice a week, and monthly phone calls designed to support and reinforce the healthy eating knowledge and behaviors gained in the first 3 months (Fig. 2).

Intervention Theoretical Framework: This pilot intervention is informed by three different theories: social cognitive theory (SCT), self-determination theory (SDT), and self-perception theory (SPT). SCT defines behavior as a dynamic and reciprocal interaction of personal factors (e.g., self-efficacy), behavior, and the environment [88–91], The intervention targets key components of the SCT to change parental knowledge, self-efficacy, outcome expectations, outcome expectancies, and perceived social support that to encourage parents to serve healthier meals and utilize positive feeding practices. This intervention uses SCT-informed behavior change techniques including active learning and mastery experiences (meal planning and preparation), vicarious experiences (through coach modeling, shared stories in materials and connection with parents on Whatsapp group), and verbal persuasion and facilitation (via coaching). It is expected that these techniques will lead to improvements in parental feeding practices and diet quality.

The use of video-feedback draws upon SPT, which states that by observing one’s behavior, people come to understand what personal attitudes or emotional responses lead to that behavior [92]. This unique approach helps parents identify how their feeding practices (both positive and negative) may influence their child’s eating behaviors. Video-feedback on parent and family food practices are used together with motivational interviewing (MI) to provide parents with increased awareness of what they are doing well and where they could use help in providing a healthier home food environment.

SDT is a theory of human motivation that explores the extent to which behaviors are autonomous (i.e., engaging in a task because it is enjoyable or personally meaningful) or controlled (i.e., engaging in a task because of outside influences) [78,93]. SDT emphasizes the quality of motivation for behavior change, suggesting that internalized motivation is more likely to lead individuals to initiate and maintain behavior change than external motivation. Since the proposed intervention is tailored to the needs of the parent, SDT is utilized as a framework that allows them to make behavioral changes based on intrinsic motivation, emphasizing autonomous vs. external influences such as rewards or pressure. In order for motivation to become more internalized, SDT posits that the environment (including behavioral interventions) needs to support three basic psychological needs: relatedness (need to feel close and connected to others), autonomy (need to feel willingly engaged in their behaviors and feel sense of ownership), and competence (the need to feel effective and capable and develop sense of mastery over their own behavior) [94]. Our intervention supports these needs through the work of community health workers, collaborative goal setting, intervention materials tailored to the needs of

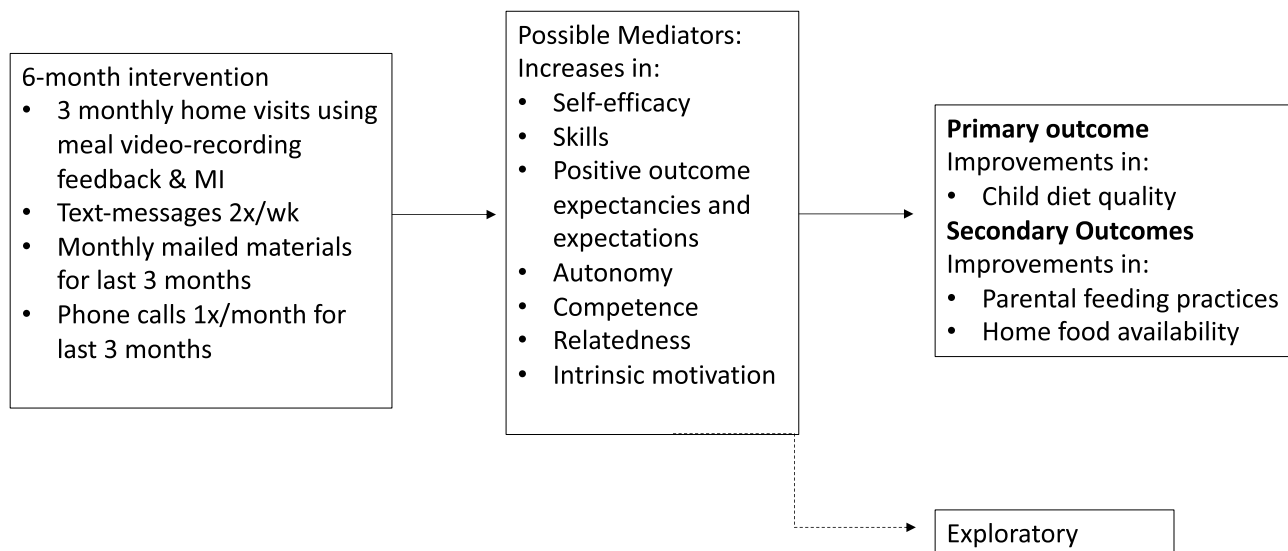


Fig. 1. Strong Families Start at Home logic model.

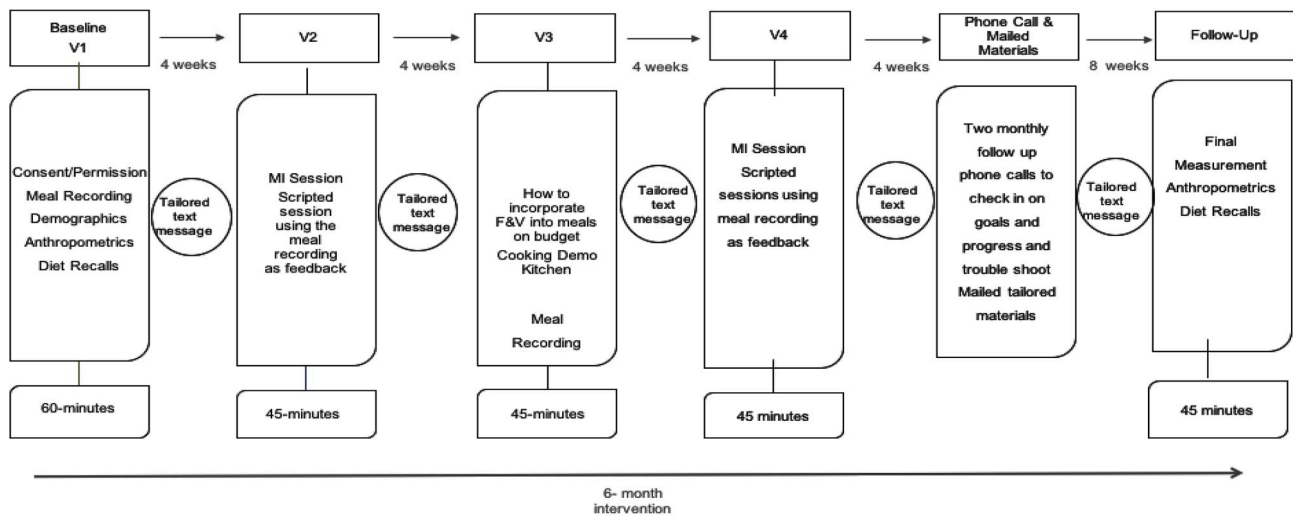


Fig. 2. Strong Families Start at Home study timeline.

the child, practical hands-on skills training in meal planning and preparation and providing a clear and meaningful rationale for activities (for example explaining how child involvement in the food preparation activity can increase willingness to consume healthful foods). The intervention also supports autonomy through MI, which focuses on acknowledging and respecting the participant’s perspective, encouraging participants to choose goals that are in line with their interests and values and minimizes the use of controlling language. Taken together, these strategies are expected to increase parental self-efficacy and motivation for serving easy, inexpensive, healthy foods in the home, leading to increased parent and child exposure to more healthy and varied foods, improvements in parental feeding practices, and ultimately, improvements in child diet quality (See intervention logic model in Fig. 1).






We constructed a matrix of change objectives to match behavioral determinants from the above theories with each performance objective to ensure that all developed content (scripts, printed materials, text

messages, social media posts) used methods and strategies that addressed determinants of motivation and behavior change in alignment with our theoretical frameworks (see example in Supplementary Table 3) [84].

3.3.1. Community health workers

Three CHW were hired to serve as lay MI counselors for the enrolled parents/guardians. CHW resided in Rhode Island and had experience working with the team on a previous study that involved MI and the control intervention but not parent feeding practices [95]. All CHW are bilingual (Spanish and English) and have experience working with low-income populations. CHW received 8 h of training in best practices in childhood nutrition and parent feeding practices provided by a registered dietitian with expertise in pediatric nutrition and feeding practices (KF). They also received 8 h of MI review training conducted by a Brown University faculty member with a PhD in psychology and extensive experience in health behavior change and MI (EJ).

Table 1 Overview and sample content of intervention components.

Intervention Component	Timing	Overview and Sample Content
In Home Motivational Interviewing and Tailored Feedback 	Visits 1,2, and 3	<p>Overview: Help caregivers identify and develop healthy food parenting practices.</p> <ul style="list-style-type: none"> Promoting healthy food parenting practices Creating family routines around healthy eating Development of children’s eating behaviors
Video Assessment 	Visit 1 and Visit 3	<p>Overview: Parents will submit a video of a family meal for personalized feedback</p> <ul style="list-style-type: none"> Highlight one positive practice the caregiver used during a meal Highlight one suboptimal practice the caregiver used during a meal Reflect on video and provide guidance
Food Preparation and Cooking Training 	Visit 2	<p>Overview: Help caregivers develop basic cooking skills or choose healthy prepared foods.</p> <ul style="list-style-type: none"> Choosing/Preparing easy healthy family meals and snacks on a budget Meal planning as way to budget family meals Including children in family meal planning and preparation
Text Messaging 	2 times/ Week (Month 1 -6)	<p>Overview: Provide caregivers with nutrition-related messaging to reinforce intervention content.</p> <ul style="list-style-type: none"> Promoting healthy food parenting practices Tips on meal planning and preparation Reinforce progress towards goals
Mailed Materials and Follow-up Calls 	Visits 4,5 and 6 (Mailed materials and phone calls 1x/month)	<p>Overview: Discuss barriers and progress towards goals and provide nutrition-related materials.</p> <ul style="list-style-type: none"> Mail nutrition-related materials based on child’s appetite traits Elicit strategies for overcoming barriers Reinforce progress towards goals

3.4. Intervention components

The primary intervention components include in-home motivational interviewing visits, video assessments, food preparation and cooking, text messages, mailed materials, and follow-up calls, which are described below and summarized in [Table 1](#).

3.4.1. Home video assessment

Prior to the first and third home visits, participants video-record their family meal and send the video to the research team via Google Drive or WhatsApp. Videos are downloaded to a secure password protected server identified only by study ID. The research team then codes the video using a coding scheme developed specifically for this project and based on key parental feeding constructs [96]. The coder then identifies video segments that are most representative of positive and negative parental feeding practices and provides those clips to the CHW along with a feedback sheet explaining what was observed and what is recommended. During the first and third home visits, the CHW brings an iPad with the meal video-recording to the home, and the CHW and parent watch the segments of the recording previously identified by the researcher. Using MI, the CHW elicit the parent’s thoughts and beliefs regarding practices used during the meal video and facilitate the development of a plan to improve these practices. In the event that parents do not send a video-recording in time for their visit, CHW utilize a sample video-recording of a parent-child highlighting examples of positive and negative practices.

3.4.2. In home visits

The three home visits include: 1) video-feedback and MI around home mealtime practices; 2) in-home cooking demonstrations; and 3) tailored in-person feedback to parents based on the child’s appetitive traits.

At each visit, the CHW uses MI to actively elicit and reinforce any language indicating the parent’s desire, ability, reason, need, or commitment to change feeding practices. MI incorporates the use of open-ended questions, affirmations, reflections, and summaries to actively involve the parent in the conversation.

Collaboratively, the CHW and parent develop a plan that includes a specific goal(s), reasons for the plan, potential barriers to completing the plan, and some possible solutions (including social supports). At all visits, the parents receive a handout that highlights the topics covered.

3.5. Printed materials

Printed materials with information on nutrition and parenting are provided to guide the CHW in discussion and goal setting at each timepoint. The first visit’s nutrition materials contain information on increasing accessibility of fruits and vegetables in the home, decreasing accessibility of nutrient poor energy dense foods, and United States Department of Agriculture My Plate guidelines. The parenting practices targeted include offering guided choices, increasing healthy role modeling, structured meals and snacks, limiting distractions at meals (i. e. screens), serving small portions, and allowing children to ask for more food. During the second visit, the CHW presents materials on the importance of the parent as a role model, ways to increase family meals and meals prepared at home, and methods to involve the child in choosing and preparing foods. During the third visit, CHWs discuss the importance of routines and limits around meals including parents determining when and where children eat, providing limited and guided choices, limiting screens at meals, and positive encouragement for desired behaviors (trying new foods). As part of these materials, there are comic strips with examples of scenarios on what parents can say during mealtimes.

3.6. Tailored materials based on child appetitive traits

During the first home visit, the first phone call, and in the mailed materials, parents receive tailored information based on their child’s eating behavior. Previous research suggests that providing tailored feedback in conjunction with MI may further enhance motivation for behavior change [58,64]. Information about the child’s appetitive traits collected via the Child Eating Behavior Questionnaire (CEBQ) [97] at baseline is used to construct tailored feedback for each parent-child dyad. The CEBQ is a validated tool that measures 8 appetitive traits in children that relate to food intake. Appetitive traits such as food fussiness, satiety responsiveness (sensitivity to internal satiety signals), and food responsiveness (sensitivity to external food cues) have been associated with BMI and measures of diet quality [28,98–106,106–104105]. Thus, these traits are important factors to consider when educating parents on how to guide their children [101]. For this study, we use 3 sub-scales: Food responsiveness, Satiety responsiveness, and Food fussiness as all have consistent associations with either BMI or diet quality [36]. Children were categorized as high in each category based on the following scores; food responsiveness >2.8, satiety responsiveness >2.8 and food fussiness >3.0 [107,108]. In addition to the written materials that all families receive, the CEBQ scores are used to identify and select additional written materials that highlight parent feeding practices that may be most responsive to the child’s eating behavior. For example, parents of children who were identified as “food fussy” receive tailored information on responsive strategies such as limiting pressure to eat, offering guided choice, increasing child involvement in food preparation, and using repeated exposure. See [Table 2](#) for sample content of tailoring by appetitive trait. If the child doesn’t fall into any of these categories, they do not receive the additional information.

3.7. Food preparation and cooking training

During the second visit, the CHW, together with a culinary intern with experience in cooking education, leads a hands-on food preparation

Table 2
Overview and sample content of Tailoring by Appetitive Trait.

Appetitive Trait	Description	Overview and Sample Content
High Food Fussiness	Rejection of many foods, both familiar and novel	<p>Overview: Highlight practices that may decrease food fussiness.</p> <ul style="list-style-type: none"> • Limiting pressure to eat • Increasing child involvement in food preparation • Repeated exposure of new foods
High Food Responsiveness	Eating in response to external cues	<p>Overview: Highlight practices that support a food responsive child</p> <ul style="list-style-type: none"> • Increasing availability and accessibility of healthy options • Decreasing availability and accessibility of energy dense nutrient poor options • Using alternatives to food based rewards.
Low Satiety Responsiveness	Poor ability to recognize and adjust eating in response to internal feelings of fullness	<p>Overview: Highlight practices that support a child with poor satiety responsiveness</p> <ul style="list-style-type: none"> • Teaching children to identify their hunger and satiety cues • Limiting distractions during meals • Offering small portions of nutritionally balanced meals and snacks.

of a recipe that was selected during the first home visit. During the session, the culinary intern engages the child in a food preparation task that is appropriate for his/her age. In addition, depending on the parent's interest, the culinary intern guides him/her on how to prepare the meal, otherwise the parent can observe the food preparation activity. The primary goals of this visit are to increase parental knowledge and skills of easy to prepare, healthy food recipes, to develop a realistic weekly meal plan with the parent, and to set goals on ways to involve children in meal planning and preparation.

3.8. Intervention incentives

Child sized plates and utensils are provided as an incentive and to reinforce the importance of offering child size portions. Cookbooks with simple, low-cost, culturally tailored recipes, measuring cups and spoons, and a child apron are provided as incentives and to reinforce the importance of increasing preparing meals at home and involving the child in food preparation.

3.9. Phone calls (Months 4, 5 and 6)

The mailed materials for the last three months of the intervention, which accompany the monthly phone calls, mirror the first three sessions in content and provide additional examples, nutrition tips, and simple low-cost recipes. During the final 3 months of the intervention, parents receive mailed or emailed monthly (depending on their preference) handouts with content that mirrors the first three visits along with additional tailored materials. Each month, parents also receive a monthly 30–45 min MI phone call from the CHW to check in on goals and barriers.

3.10. Ongoing text messaging

This study component uses a text-messaging system that can communicate with RedCap. Text-messages are sent two times/week with messages relating to the performance/change objectives targeted during that month's visit. Content for text messages was developed using data from focus groups and USDA My Plate consumer message guidelines [26]. Examples of text-messages include: 1) *Your kids look up to you! Set a good example by eating fruits and vegetables every day.* 2) *Parents provide and kids decide. If you are offering healthy meals and snacks to your child, you are doing your job!* 3) *Kids are easily distracted. Turning off the TV or tablet at mealtimes can help them focus.* Links to recipes and video clips of easy food preparation are also included.

Participants are also given the option to join a private group on Whatsapp where additional materials related to the intervention materials are posted twice a week, and where they are able to interact with other parents from the intervention group.

3.11. Attention control group

The comparison receives an attention-matched intervention about school readiness promotion that has been adapted from R.E.A.D.Y. (Read Educate and Develop Youth) designed by the Michigan Department of Education [109–111]. Parents receive the same intervention components as the intervention group, pertinent to school readiness instead of nutrition. This includes video assessment of a parent reading or completing an activity with their child during home visits 1 and 3, an activity related to reading during home visit 2 and the three-monthly phone calls during the final three months of the study to check in on progress related to their goals. Parents also receive text-messages based on these materials as well as print materials during the final three months of the intervention. Materials include information on helping parents prepare their children for language development such as talking to them, singing to them, helping them identify words and sounds and making sure they read with their child. Instead of receiving cooking

materials as an intervention incentive, they receive a set of children's books.

4. Evaluation study methods and measures

4.1. Recruitment/study sample

A total of 60 participants (30 intervention and 30 attention control) are being recruited through a variety of active and passive recruitment strategies. For active recruitment, selected WIC nutritionists in Rhode Island have been human subject certified to recruit within their offices by asking parents if they would be interested in participating in a research study. If parents are interested, the nutritionist records their name and contact information, which is passed to research staff for follow-up. Study staff also recruit parents in WIC waiting rooms or child welfare organizations and invite parents who previously participated in focus groups. Passive recruitment strategies include placing flyers and sign-up sheets in childcare settings and doctors' offices. When parents indicate interest in the study, research staff provide them with a brief description of the study and, if still interested, assess eligibility.

To be eligible, the parent must be the primary caregiver, be at least 18 years old, speak English or Spanish, have a child between 2 and 5 years of age and have a phone that is able to video-record. Parents are ineligible if their child has a severe feeding disorder (assessed by asking parents if their doctor or WIC provider has diagnosed a feeding disorder). At the time of recruitment, if interested and eligible to participate, research staff schedule the baseline home visit.

4.2. Data collection

At the 90-min home measurement visit (baseline and 6-month follow-up), the parent provides informed consent for both parent and child participation. Then, trained study staff administer a questionnaire that includes demographics, feeding questions, home food inventory and other health behaviors. They also measure the parent and child's height and weight, and complete one of two 24-hour dietary recalls [112] as described below. All questionnaire data is managed using RedCap electronic data capture tool hosted at the University of Rhode Island [113]. Upon completion of the baseline visit, parents receive a \$35 gift card and study staff schedule a second dietary recall to be completed over the phone (see details below). After completing the second recall, participants are randomized into the intervention or control group, and are compensated with a \$15 gift card. At follow-up, participants receive a \$50 gift card for the measurement visit and \$35 for completing the second recall. Data collectors are blinded to experimental condition.

4.3. Randomization

Study staff use sequentially numbered, opaque, sealed envelopes to randomize participants. Participants are allocated to one of the two groups in a 1:1 ratio using block randomization with 10 permuted blocks of size 6 in each stratum. Randomization is then stratified by ethnicity to achieve balance between groups. Participants are told which group they are in at the end of the second recall, after which time the first home visit is scheduled. Every effort is made to conduct the second recall, but if it has not been scheduled within two weeks of completing the first recall, participants are randomized at that time without the second recall.

4.4. Measures and outcomes

Primary Outcome: Child Diet Quality. Data to calculate children's diet quality are derived by averaging the two 24-h dietary recalls to represent typical intake at each timepoint. This method is considered to be a gold standard in assessing effectiveness of an intervention study to change dietary intake. We use the recommended multiple pass approach

to provide multiple opportunities for the participant to recall food intake. During the first pass, the parent is asked to recall all foods the child ate over the previous 24-h. In the second pass the list of foods is reviewed for completeness and correctness. Details are obtained regarding portions consumed, methods of preparation and any additions made to the food in the third pass. During the fourth pass participants are probed for commonly forgotten foods. Finally, in the fifth pass all foods entered are reviewed a final time for completeness and correctness. Dietary supplement use was assessed using the Dietary Supplement Assessment Module included in NDSR [114]. The bilingual Food Measurement Aids for Infants and Toddlers are used to estimate portions or volume of foods and beverages consumed [115]. This food model booklet is appropriate for the diets of preschoolers as well as infants and toddlers. When parents use this tool to quantify a food or beverage, study staff use a conversion guide to determine how to enter the quantity of a reported food into the database. Parents can also quantify foods and beverages using household measuring cups and spoons, food labels or packages, or by describing standard-size foods [116]. All foods and beverages are entered into the Minnesota Nutrient Database for Nutrition Research (NDSR) for analysis software, derives nutrient and food data from the recalls. The protocol is to conduct dietary recalls on one weekday and one weekend day to reflect changes in dietary patterns on weekdays vs weekends. If the first two attempts to schedule as such are unsuccessful the second recall are scheduled at the parents' convenience.

Caloric intake and macronutrient content as well as the Healthy Eating Index-2015 (HEI) total and component scores (total fruit, whole fruit, total vegetable, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids, refined grains, sodium, added sugars, and saturated fat) [117,118], are derived using established methods and publicly available USDA SAS codes. The total HEI score ranges from 0 to 100 with higher scores reflecting higher diet quality, and a score of 80 reflecting a high-quality diet among preschool aged children [119]. Dietary data undergoes quality assurance procedures completed by trained research assistants and supervised by a registered dietitian. Data is exported and analyzed for outliers or implausible values.

We expect that our proposed intervention will improve total HEI by 5 units [120]. We selected 5 HEI units based on the following rationale: (1) 5 HEI units is clinically meaningful; it predicts a 4–6% decrease in overall mortality [121] and a 15% decrease in the prevalence of obesity [122]; (2) 5 HEI units is statistically meaningful; it is approximately 0.5 of the standard deviation of HEI when measured in large, representative samples; and (3) 5 HEI units is a reasonable expectation for a moderately intensive intervention; with previous research reporting increases ranging from 3.6 to 7.8 [123].

4.5. Secondary outcomes

Parental Feeding Practices: The Food Parenting Inventory, a questionnaire to measure parental feeding practices has shown good initial evidence for the reliability and validity among Hispanic caregivers. The confirmatory factor analyses showed a good fit for three food parenting domains —encourage trying new foods, mealtime structure, and external control. The items loaded highly on these factors and all of the inter-item correlations were acceptable [124]. We will explore pre-post changes to 14 subscales of this measure: Encourage try new foods, Encourage exploration of new foods, Urge child to eat new foods, Repeated Presentation of New foods, Family meals, Regular timing of meals and snacks, Inconsistent mealtimes, Indifferent feeding, Child involvement in food preparation, Pressure to Eat, Restriction, Food as a reward, Responsiveness to child's fullness cues, Monitoring, and one subscale of the Comprehensive Feeding Practices Questionnaire [125], Healthy Eating Guidance. Items are rated on a 5-point Likert scale ranging from 1 (*never*) to 5 (*always*) and 1 (*disagree*) to 5 (*agree*). Higher subscale scores indicate greater use of that child feeding practice.

Home Food Availability: A short home food inventory (HFI) assesses a wide range of commonly available foods in the home environment during the baseline visit and follow-up visit. The research staff ask to inventory the foods in the kitchen. The HFI includes 13 food categories (e.g., fruits and vegetables, candies, cookies) [126]. HFI items are listed in a checklist format and include yes/no options. Additional options include whether fruits and vegetables are fresh, canned/jarred, frozen, or dried [126].

Covariates/Potential Moderators: Parents complete a demographic questionnaire where the following information is collected: parental age, race/ethnicity, marital status, income, birth country, years in the US, diet [127], household composition, household chaos [128], and child age, gender, BMI, and childcare attendance. We will use standard techniques for measuring parent and child height and weight [129] and will calculate BMI, and percentage of children and parents in risk categories.

Exploratory Measures (possible mediators): Because this is a pilot study and not powered to explore mediation and moderation, the following were collected as exploratory measures (see logic model visualized in Fig. 1). Parents' basic psychological needs satisfaction and frustration [130] is measured using a 24-item survey that has been validated in culturally diverse samples of adults with good internal consistency, construct validity and predictive validity. The socio-emotional context of feeding [131] is measured using Parent Socioemotional Context of Feeding Questionnaires (PSCFQ), a 24-item measure validated in mothers of 4-8-year-old children with good internal consistency and construct validity. Parents perceived competence [132] is assessed using a 4 item questionnaire that assesses the degree to which participants feel confident about being able to make or maintain a change in feeding their children in healthy ways. Additional child health behaviors are captured by the Healthy Kids survey, a 45-item tool that assesses child nutrition, sleep, screen time, and time spent playing outside [133]. A brief language checklist developed specifically for this study is also used to assess any changes in behavior as a result of the control intervention.

4.5.1. Process evaluation

Implementation fidelity and acceptability for each intervention component are measured [134,135]. Fidelity includes measures of dose and adherence/quality. Dose includes the number of CHW home visits completed (measured by attendance records, length of visits), text-messages received, number of written materials read (measured by questions on the follow-up survey), and number of CHW phone conversations completed (measured by call logs). Adherence/Quality of communication between the CHW and parent is measured by audio-recorded home visits and phone calls as well as by parent responses on the follow-up surveys. The Motivational Interviewing Treatment Integrity Code (MITI 3.1.1) is used to determine CHW MI adherence [136]. A trained rater randomly codes 10% of the sessions, selecting 20-min segments of the recorded sessions using the MITI 3.1.1. A second trained rater double codes a selection of these sessions. To measure acceptability, parent satisfaction with the intervention components and any unintended consequences are assessed through follow-up surveys. Follow up interviews with the CHW are conducted to learn about their experiences with delivering the intervention, major challenges and anecdotal successes. During the final home visit, parents are asked about their opinions related to the acceptability of the intervention as well as any other additional feedback that would inform the larger efficacy trial.

Feasibility and Acceptability: We will consider the intervention feasible if at least 80% of participants are retained at the 6-month follow-up. We will also ask participants which intervention components they used in order to capture demand. The intervention will be considered acceptable if at least 80% of participants respond favorably ("satisfied" or "very satisfied") to the question: "In general how satisfied were you with the intervention?" We will also conduct post intervention

interviews with select participants to better understand what worked, what they liked and did not like from the intervention.

4.6. Statistical analysis

We will assess for potential between-group differences in baseline characteristics (demographics) using graphical methods, non-parametric and parametric tests as appropriate (e.g., Wilcoxon rank-sum test for skewed data, t-tests for normally distributed continuous data and chi-squared tests for categorical data) and variables found to be important covariates will be included in subsequent analyses. We will estimate the preliminary efficacy of the intervention compared to comparison using a generalized linear model in which we will compare 6-month HEI, feeding and food availability between study conditions, while controlling for baseline HEI, feeding and food availability scores and potential confounders (as mentioned above). Modeling will be done using a likelihood-based approach and thus makes use of all available data. We are aware that effect size estimates with small samples have large standard errors and wide confidence intervals.

4.7. Sample size and power estimates

In order to achieve a sample of 50, assuming 20% attrition, are recruiting 60 parent-child dyads. This sample is appropriate for a pilot study that seeks to establish feasibility and identify problems in the intervention or evaluation design [137]. Estimation of robust effect sizes for a future RCT would require considerably a larger sample ($n > 100$), which will be employed in the future full-sized study. The effect size achieved between groups in this pilot will be used to estimate sample sizes needs for a future RCT, though it is acknowledged that pilot studies are often too small for robust estimates [137,138].

5. Discussion

The pilot study is assessing the feasibility and acceptability of a novel video-feedback home-based intervention with low income, ethnically diverse families, and determining the preliminary efficacy of the intervention on changes in children's diet quality (primary outcome) to calculate effect sizes for a future RCT. Given the continued need to reach low-income ethnic minorities with dietary interventions, we believe this work can lay the groundwork for a future RCT to reduce disparities in health behaviors.

We expect that there will be some hurdles to overcome throughout the study. First, recruiting and retaining families could be challenging. However, in our pilot study as well as our other previous research [79, 139,140], we had success with both recruitment and retention. Given our strong partnership with WIC, our work with our CAB and their ability to reach families throughout the state, we believe that our recruitment will not pose major challenges. If recruitment is a challenge, we will work to recruit parents through other existing partnerships. With regards to retention, we will call participants and discuss barriers to participation, send welcoming messages to both groups (for example-happy birthday wishes), and provide incentives. In our pre-pilot, all of the mother-child dyads were retained for three months [141–146].

Second, cooking demonstrations may be difficult within participants' homes if there is a lack of kitchen space and equipment; however, we have budgeted incentives in the form of kitchen supplies to help overcome this. In addition, we ensure that all recipes are appropriate for the space and equipment available, e.g., if a family does not own a microwave, we will not include microwave recipes. Although historically home-based interventions have been critiqued for being costlier, if three home visits lead to change in certain behaviors, then this intervention may be more cost-effective vs. having a longer, less intensive approach. As recently reviewed, home-based approaches hold promise and have the potential to be scaled up within different systems including WIC and

home-visitation programs [77]. Cost effectiveness could be assessed in future studies if the pilot intervention is found to be feasible and acceptable.

We believe this pilot study has many strengths that may lead to improvements in children's diet quality, an important public health issue associated with many health problems including obesity, diabetes and cardiovascular disease. First, the study focuses on underserved families who often have lower diet quality and higher obesity rates [147–149]. Second, the intervention consists of an innovative meal video-recording and hands-on home-based approach that may be especially appealing to busy families. Third, the study harnesses the capabilities of cell phone technology via novel meal video-recording and text-messaging to serve as a personal and relevant starting point for a discussion on parental feeding practices. Fourth, the intervention is tailored based on the child's appetitive traits, which is novel and increases the likelihood for efficacy. Fifth, the intervention is theory-based and is informed by formative research with the target population. Finally, the study uses a randomized, experimental design and validated measures, including gold-standard 24-h recalls. Further, having strong community partnerships and a CAB will assist with intervention adaptation and study implementation.

If successful, this pilot should be tested in a larger randomized controlled trial design. If shown to be effective in improving child diet quality, the RCT would lay the foundation to incorporate the intervention into existing home visiting programs targeting preschool aged children, such as Parents as Teachers, Early Intervention, and Healthy Families of America.

Acknowledgements

This work is funded by the National Heart, Lung, and Blood Institute NHLBI 1R34HL140229-01A1.

KF is supported by USDA Hatch/Tovar/1001894.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2020.100583>.

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