Published in final edited form as:

Contemp Clin Trials. 2013 March ; 34(2): 187–195. doi:10.1016/j.cct.2012.11.004.

The Community-based Healthy-lifestyle Intervention for Rural Preschools (CHIRP) Study: Design and Methods

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Abstract

The CHIRP Study is a two-arm, pilot randomized controlled trial assessing the effectiveness of a behavioral family weight management intervention in an important and at-risk population, overweight young children, 3 to 6 years of age, and their parents from underserved rural counties. Participants will include 96 parent-child dyads living in rural counties in north central Florida. Families will be randomized to one of two conditions: (a) Behavioral Family Based Intervention or (b) a Waitlist Control. Child and parent participants will be assessed at baseline (month 0), post-treatment (month 4), and follow-up (month 10). Assessments and intervention sessions will be held at the Cooperative Extension office in each participating rural county. The primary outcome measure is change in child body mass index (BMI) z-score. Additional key outcome measures include child dietary intake, physical activity, and parent BMI.

This study is unique because (1) it is one of the few randomized controlled trials examining a behavioral family intervention to address healthy habits and improved weight status in young overweight and obese children, (2) addresses health promotion in rural settings, (3) examines intervention delivery in real world community settings through the Cooperative Extension Service offices. If successful, this research has potential implications for medically underserved rural communities and preventative health services for young children and their families.

Keywords

Obesity; Young Children; Behavioral Intervention; Treatment; Randomized Controlled Trial

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1. Introduction

Approximately 25% of children ages 2 to 5 years are overweight or obese [1]. Obese children are at greater risk for developing a variety of health and behavior problems [2–10]. The early childhood home environment is crucial in establishing knowledge and practices consistent with energy balance and healthy weight. Parents are largely responsible for establishing early physical activity and eating patterns for children [11]. Unfortunately, in early childhood dietary habits are often poor and inconsistent with national guidelines [12, 13]. Obesity at young ages is positively associated with the consumption of larger portion sizes of energy-dense foods, greater energy intake, and less physical activity [14, 15]. Alternatively, consistent exposure to vegetables, greater dairy intake, and an authoritative parenting style are positively associated with healthier weight status [16, 17]. Addressing these patterns during early childhood is vital to reducing risk factors for obesity and disease over the life span [18].

There is a dearth of studies examining the effectiveness of obesity prevention programs for preschoolers [19]. Most studies targeting eating and physical activity in young children are delivered in preschool or childcare settings [19] and do not include a parent component, which limits the impact on the home environment. Behavioral family interventions (BFIs) have been the most studied intervention for pediatric obesity and have produced the best results [20, 21]. These programs target the child and parent for weight management by addressing dietary intake and physical activity through parent modeling, skill building, and behavioral modification strategies [21]. BFIs are well suited to helping parents establish a home environment conducive to supporting healthy eating and physical activity patterns. Most research with BFIs has been conducted with school-age children [20, 21]. Only one randomized controlled trial (RCT) has been published reporting on a BFI to address weight management in obese preschoolers [22]. Specifically, Stark and colleagues reported that their 6-month combined clinic and home-based behavioral family intervention led to significantly greater improvements in child BMI z-score (-0.59 ± 0.17) relative to a pediatrician counseling control group at post-treatment. Therefore, a logical step to address the obesity epidemic in the U.S. is the development of additional BFIs that are tailored for families of young children and delivered in community-based, real world settings.

Citizens of rural areas represent one of the largest medically underserved populations in the country. Compared to urban populations, rural residents are slower to adopt lifestyle changes related to improving behavioral risk factors for obesity [23, 24]. Not surprisingly, children and adults from rural areas experience higher rates of obesity and associated health risks relative to non-rural individuals [23, 25–29]. There are few RCTs utilizing prevention or intervention programs to address obesity in rural children.

While BFIs have been rigorously evaluated [20, 21], the generalizability of these interventions is less clear. Many of these programs have been tested in well-controlled, university medical centers by highly-trained clinical researchers. The only published RCT examining a BFI with obese preschool aged children was conducted in such a setting [22]. Few trials have been conducted in medically underserved community settings or in rural communities with treatment delivered by local staff. Given the scope of obesity in rural America, the lack of intervention studies highlights the pressing need for a clinical trial targeting obesity for younger rural children.

2. Objectives of the CHIRP Study

The CHIRP Study is funded by a grant from the National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK) for Home and Family Based Approaches for the Prevention and Management of Overweight and Obesity in Early Childhood (R21). The

study builds on our previous work focusing on evaluating the effectiveness of family based weight management interventions for school-age children and their parents from rural communities [30, 31], which were also funded by NIDDK. The primary aim of the study is to evaluate the effects of a BFI delivered via group contacts to overweight and obese young children and their parents in rural counties on children's standardized body mass index (e.g., BMI z-score) to a Waitlist Control condition. Secondary aims include: (a) examining changes in child dietary intake, fruit and vegetable consumption, and physical activity, (b) evaluating the effects of the intervention on parent body mass index, and (c) examining potential moderators and mediators of change in child weight status.

The current project is an exploratory and developmental study (R21) that, if successful, will provide pilot data to develop and support a grant application for a full-scale RCT (R01). The full-scale RCT will build on the current pilot study by incorporating: (a) a larger number of participants and rural community intervention sites, (b) incorporation of individual family sessions and maintenance sessions, (c) a longer follow-up period, and (d) assessment of biological markers of relevance to obesity risk factors in younger children (e.g., development of diabetes, cardiovascular risk factors).

3. Study Design

3.1 Overview

Participants will include 96 overweight or obese preschool age children, ages 3 to 6 years, and their parent(s)/caregiver(s) from six rural counties in north central Florida. Families will be treated in two successive cohorts, each consisting of about 48 child-parent dyads across three counties per cohort. Within each county approximately 16 families will be randomly assigned to either a 4-month long Behavioral Family Intervention (BFI) or a Waitlist Control (WLC) condition. The BFI will include simultaneous but separate group meetings for both the target child and parent. Dyads in the WLC will complete assessment measures according to the same schedule as those in the BFI condition. These families will receive treatment after the completion of the 6-month follow-up assessment (month 10). At least 25% of the sample will be families from racial or ethnic minority groups. The study protocol was approved by the governing institutional review board.

3.2 Rural Areas

Criteria established by the Office of Management and Budget (OMB) were used to define rural areas. The OMB categorizes counties based on population size and incorporation with large cities [32]. Non-metropolitan counties (i.e., "rural areas") are categorized as either a rural county with a city population no larger than 50,000 or a rural area without a city. The six counties participating in the CHIRP study are considered rural according to the OMB. In addition, they have been designated in whole or in part as a "health professional shortage area" by the U.S. Department of Health and Human Services Health Resources and Services Administration [33].

3.3 Cooperative Extension Service

Similar to our previous randomized controlled trials conducted in rural counties [30, 31], the CHIRP Study will be conducted through the Cooperative Extension Service (CES) network in participating rural counties. The CES is a joint venture between the U.S. Department of Agriculture (USDA), land-grant universities, and local county governments to provide communities throughout the country with access to research based information. Examples of CES programs include educational programs related to agriculture, natural resources, family and consumer sciences, and youth development (e.g., 4H). The CES provides infrastructure, link to resources of land-grant universities in each state, prominence in rural communities,

and knowledge of ways to provide prevention and intervention efforts to children and families from rural communities. All assessment, intervention, and follow-up components of the CHIRP Study will be administered through contacts at the CES office in each participating rural county.

3.4 Inclusion Criteria

Children between the ages of 3 and 6 years, with a BMI equal to or above the 85th percentile for age and gender, will be eligible for the study. The child and participating parent(s) or legal guardian(s) are required to live in the same home as the child and reside in a rural county. Participating parents or legal guardians must be 75 years old or younger. Participants (children and adults) are required to obtain physician approval to participate in the study, with documentation provided via letter signed by a physician medically clearing them to participate in a weight management program. For families who are not able to access physician care, an appointment with a physician will be arranged at no charge to the family.

3.5 Exclusion Criteria

Families will be excluded from the study if the child or participating parent has a dietary or exercise restriction, or a medical condition that contraindicates mild energy restriction or moderate physical activity. These include a history of a musculoskeletal condition that limits walking; heart condition; chronic lung diseases limiting physical activity; uncontrolled high blood pressure; thyroid disease; or uncontrolled exercise induced-asthma as determined by a physician. Children or participating parents on antipsychotic agents, systemic corticosteroids, antibiotics for HIV or tuberculosis, chemotherapeutic drugs, or those who are currently using prescription weight-loss drugs will also be excluded from study participation. This information will be assessed via parent report during the initial phone screening and verified in the initial in-person screening visit. Children or adults cannot be engaged in another weight control program. In addition, families will be excluded if they exhibit conditions or behaviors that are likely to affect their participation in the trial, such as being unwilling or unable to give informed consent, parent(s) or legal guardian(s) unable to read English at approximately the 5th grade level, unwilling to accept random assignment, unable to travel to the CES office for assessments and intervention sessions, or likely to move out of the county within the next 12 months.

3.6 Family Participation

All participating children must be accompanied by a parent or legal guardian. One or both parents (or legal guardians) can participate in the intervention program. Ideally at least one parent will consistently attend the program, instead of parents switching off from session to session. Siblings will not be allowed to attend treatment group sessions; however, child care services will be available on-site for families who need assistance in caring for other children during group intervention sessions.

3.7 Recruitment and Retention

Recruitment will take place over a four-month period prior to the beginning of treatment groups in each wave. We will recruit and randomize a study sample that broadly represents the population of families with children 3 to 6 years old in rural north central Florida. Treatment groups within each county will occur on a specific weeknight (Monday, Tuesday, Wednesday, or Thursday). Rural communities often are very close-knit and residents can be hesitant to trust individuals from outside the community [34]. Therefore, we will work closely with CES personnel as collaborative partners to help build acceptance within the community. Recruitment will entail direct solicitation methods including direct mailings,

distribution of brochures through local preschools and elementary schools, newspaper press releases, local physician offices, and presentations at community events. Prospective participants will be invited to learn more about the study by calling our toll-free telephone number. A trained member of our research team will make follow-up phone calls to describe the study and to perform a brief screening for eligibility. Families that express interest and meet initial eligibility criteria will be scheduled for an inperson screening visit. At the initial screening visit child and parent dyads will complete informed consent procedures, measures of height and weight, medical history questionnaires, and other health status and psychosocial questionnaires. Families who meet eligibility criteria at the in-person screening visits will be invited back for a baseline assessment visit that will occur within three weeks of treatment initiation. Assessment of outcomes measures at the baseline, post-treatment and follow-up assessment visits are described in Section 3.9. Families will be notified of their treatment assignment at the completion of the baseline assessment visit.

Retention of families in weight management intervention trials can be a significant challenge for researchers. Similar to our previous studies [30, 31], we plan a proactive approach to retention during the treatment protocol that includes: (a) having study interventionists and the PI meet on a weekly basis to discuss the progress of each family in order to devise individualized plans; (b) making follow-up phone calls immediately after missed sessions and attempting to schedule make-up sessions; (c) allowing staff to compromise with participants for agreed upon goals; (d) limited emphasis on monitoring lifestyle behaviors for families that experience difficulties; and (e) providing payment (\$10 per treatment session attended) to help offset transportation costs. It is expected that this proactive approach will also be helpful in improving adherence to the treatment protocol, ultimately having positive impacts on participant attendance, retention, and study outcomes. Furthermore, families will receive \$25 for completing the post-treatment (month 4) assessment and an additional \$50 for completing the 6-month follow-up (month 10) assessment.

The retention of waitlisted families during the initial intervention, as well as all participants during the 6-month follow-up period, is another potential challenge. To assist with long-term retention we plan to send out quarterly newsletters with information about upcoming assessments and the beginning of treatment for families assigned to the WLC group, as well as birthday cards. For dyads in the WLC, we will also emphasize that information from the first groups will be used to develop an enhanced program for their families.

3.8 Randomization

In each county, recruitment will continue until approximately 16 families are ready to proceed with randomization. The protocol will be to randomly assign 8 families to each of the two groups (BFI or WLC) based on stratification by child age (e.g., 3 and 4 years in one block and 5 and 6 years in the second block). Families will receive their randomization assignment after the completion of the baseline assessment. Randomization to treatment group will be conducted by our study statistician, who will have no contact with families or our baseline assessment data.

3.9 Assessment and Outcome Measures

Assessments will be conducted at baseline, post-treatment (month 4), and 6-month follow-up (month 10) at the CES office in each participating county. All measures listed below will be completed at these three assessments unless otherwise indicated below. See Table 1 for the schedule of assessment measures that will be administered to participants throughout the trial.

- *Medical History and Current Medication* use for both the child and parent will be completed by the parent at the screening, post-treatment, and 6-month follow-up assessments. At the follow-up assessments this will include child and parent medication use at any point during the months preceding the assessment.
- *Height and Weight* will be measured for both the child and parent during all assessments by trained research personnel. Height without shoes will be measured to the nearest 0.1 cm using a Harpendon stadiometer. Weight will be measured to the nearest 0.1 kg using a calibrated and certified digit scale with one layer of clothing on, without shoes, and with pockets emptied. Each measure will be completed three times, with the average used for data analysis.
- *Child Waist Circumference* will be measured by a trained member of our research team at the hipbone to the nearest 0.1 cm.
- *Child Dietary Intake* will be assessed via parent report using the Block Questionnaire for Ages 2 to 7 years – 2004 Food Frequency Questionnaire (FFQ) to estimate child daily dietary intake [35]. The food list for this questionnaire was developed from the NHANES III 1999–2002 dietary recall data and the nutrient database was developed from the USDA Nutrient Database for Dietary Studies, version 1.0. Also, 25% of the sample of parents will complete three 24-hour recalls of their child's dietary intake over a 2-week period at each assessment using the multiple pass method [36]. This method has been validated against doubly labeled water and deemed accurate for young children [37, 38]. Daily caloric intake will be calculated using Minnesota Nutrient Data Systems software [39]. Dietary recalls will be completed by a member of the research team trained in the use of multiple pass methodology to assess dietary intake. Both methods of assessing child dietary intake will be used to assess the validity of the FFQ in the sample.
- *Child Physical Activity and Energy Expenditure* will be measured via the Actigraph Activity Monitor. Children will be asked to wear the actigraph for seven consecutive days, 24 hours a day (except when bathing or swimming). Actigraphs provide information about energy expenditure and activity levels. Reliability and validity of the Actigraph have been documented in preschool age children [40, 41].
- *Child Television Time* will be assessed with a seven day television diary completed during the seven days following each assessment, in conjunction with collection of actigraph data. This is a one-page questionnaire created for use in this study. At the end of each day the parent will record how many hours/minutes their child spent watching television that day.
- *Parent Dietary Intake* will be assessed with the Block Brief 2000 Food Frequency Questionnaire. Parents will complete this measure. This is a revised version of a previously validated survey that asks respondents to estimate consumption of a wide variety of foods. Scoring yields estimates of macro- and micro-nutrient intake, as well as intake by specific food group [42].
- *Parental Feeding Practices* will be measured via parent report using the Comprehensive Feeding Practices Questionnaire (CFPQ) [43]. The CFPQ is a 49-item questionnaire that assesses verbal and physical parent feeding strategies for children 2 to 8 years of age. Parents are asked how often they implement the strategies during meals on a 5-point Likert scale ranging from “Never” to “Always.” The measure has 12 subscales and has good reliability and validity.
- *Child Behavioral Problems* will be assessed by the Eyberg Child Behavior Inventory (ECBI) [44]. The ECBI is a 36-item measure designed to assess parental report of behavioral problems in children ages 2 and older. It measures the number

of difficult behavior problems and the frequency with which they occur and has good reliability and validity.

- *Child Mealtime Behavior* will be measured using the Behavioral Pediatric Feeding Assessment Scale (BPFAS) [45], which is a 33-item scale that assesses the behavior of young children, ages 1 to 7 years, during mealtimes. Via this measure parents will be asked how often their child engages in various eating behaviors on a 5-point Likert scale ranging from “Never” to “Always.” Parents then indicate, “Yes” or “No,” if each behavior is a problem for them. The scale has adequate psychometric properties.
- *The Home Food Environment* assessed using the Home Food Inventory (HFI) [46]. The HFI examines the availability of various foods in the home and was designed for community-based behavioral nutrition and obesity research. The measure has demonstrated good construct and criterion validity.
- *Treatment Satisfaction* will be assessed during the post-treatment assessment for families who participated in the BFI. Parents will be asked to fill out a questionnaire assessing their satisfaction with various aspects of the program.
- *Barriers to Treatment Participation* will also be completed by parents in the BFI group at the post-treatment assessment. They will complete a 15-item checklist regarding situations and events that may have made group participation a challenge for their family.

3.10 Additional Measures of Treatment Adherence

Adherence to the BFI dietary and physical activity protocol and goals will be assessed via parent completion of monitoring forms and implementation of behavior change. Parents will be asked to monitor their child’s food for specific meals on a daily basis throughout the program. Parents will also track their personal dietary intake on their own food log. Parents will be trained to complete the daily food log during the second treatment group session. At this time, parents will be asked to monitor what they and their child eat and drink during one meal. The monitoring of additional meals and snacks, as well as other lifestyle behaviors (such as physical activity and sedentary behaviors) will be incorporated into later sessions. The information obtained through monitoring will be used by parents and interventionists to identify ways that children and parents can make changes to specific aspects of lifestyle behaviors, such as incorporating more fruits and vegetables, choosing healthier snacks, and identifying times to engage in physical activity.

3.11 Data Analysis

For the primary analysis, a mixed model repeated measures analysis of variance will be used with baseline and 10 month follow-up as the primary endpoints. We will follow an intent-to-treat approach to handle missing data, analyzing all participants randomized and including dropouts in our analysis. Our handling of this data is based on a missing at random assumption, which is rendered more plausible by including baseline covariates in the mixed effects model.

3.12 Power and Sample Size Calculations

Forty-eight child-parent dyads per intervention arm will be randomly assigned. Anticipating a dropout rate of 25% over 10 months, we expect 36 dyads per arm to complete follow-up. The primary outcome is change in BMIz. A primary goal of this study is to determine an effect size to power a larger intervention trial. However for this pilot study, based on previous published research [22] we expected at least a mean change in the BFI group of -0.10 , and a mean change in the control group of $+0.09$. With a pooled standard deviation

of .25 this equates to a standardized effect of 0.76 standard deviations. With 36 dyads per arm, we have 88% power to detect a standardized effect of 0.76 standard deviations, assuming a two-sided level 0.05 hypothesis test. We have 83% power to detect an effect of 0.70 standard deviations. Our estimates are much more conservative than the mean change observed by the children in both the intervention and control conditions reported by Stark et al. [22].

4. Intervention

4.1 Interventionists

The intervention in the CHIRP Study will be delivered by Extension Family and Consumer Sciences (FCS) agents, in collaboration with a post-doctoral clinical psychologist and graduate students in clinical health psychology. FCS agents are typically employed by CES offices to deliver nutrition education and other FCS programs. They typically have a Bachelors or Masters degree. All interventionists for the CHIRP Study will undergo 12 hours of training in the treatment protocols. Training will incorporate key developmental considerations in working with young children such as behavioral management, the importance of hands-on activities and repetition, flexibility in expectations for daily dietary intake, development of food preferences, and helping parents implement these skills. The interventionists will participate in weekly meetings with the PI to review each family's progress, discuss group interactions, and prepare for the next group session. Intervention sessions will be audio-taped. Random reviews of 20% of the sessions will be carried out by trained team members to assess treatment fidelity.

Sessions will be audio recorded to allow the principal investigator to monitor each interventionist's performance and assess treatment fidelity. The interventionists also will participate in weekly supervision meetings with the PI to review each family's progress, discuss group interactions, and prepare for the next group session.

4.2 Behavioral Family Intervention (BFI)

Dyads in the BFI will participate in weekly sessions for the first 8 weeks, then 4 biweekly sessions over the next 8 weeks for a total of 12 sessions during a 4 month period. Children and parents will participate in separate but simultaneous meetings that will last about 75 minutes. All treatment sessions will be conducted at the Cooperative Extension office in participating counties. Children and adults will be encouraged to eat a well-balanced diet based on the USDA's dietary guidelines and MyPlate. Within this guiding framework, the primary objectives for children and parents will be to eat a balanced diet with caloric intake consistent with USDA age and gender guidelines and to increase moderate intensity physical activity. As parents are conceptualized as the primary agents of change, much of our intervention will be centered on: (a) helping parents create a healthy home environment; (b) equipping parents with the skills and knowledge to prepare fast, affordable, healthy meals; and (c) teaching and practicing parenting skills to help overcome child resistance. Our approach for the child component of treatment is to create a fun, activity-based environment where they are introduced to information on healthy foods and opportunities to be physically active in an age appropriate manner. The intervention will be tailored for each family and will target gradual reductions in high sugar beverages and other nutrient poor, energy dense foods while focusing on consistent intake of fruits and vegetables, whole grains, and low fat dairy foods to amounts more consistent with the USDA guidelines. Dyads will be taught to eat appropriately portioned meals based on the updated USDA MyPlate recommendations. Group leaders will work with parents at each session to establish specific plans for change and then assess their success in implementing such plans. Specific plans for making healthy substitutions and environmental changes may include serving more fruits and vegetables,

detailing specific new foods a child will be exposed to in the next week, establishing plans for physical activity, outlining healthier options to select when eating out, specific behavioral parenting skills to provide support to a child trying new foods, or offering breakfast every day. Detailed descriptions of the parent and child group are provided below. See Table 2 for the schedule of BFI session topics in the CHIRP Study.

4.2.1 Parent Group—Each session will last 75 minutes and will include 4 segments. First we will review progress in implementing the specific plans for change developed during the previous session(s). Parents will describe progress they and their child have achieved and problems they encountered. Difficulties reported by parents will be managed through group support and problem solving. The second segment will focus on knowledge and skills training related to nutrition, physical activity, and establishing a healthy home environment. Additional topics that may be especially relevant to younger children include: (a) using planned exposures, gradual shaping, and positive interactions to increase willingness to try a variety of healthy foods; (b) managing resistance and inappropriate mealtime behaviors; and (c) establishing safe places for active play. Third, parents and group leaders will work together to make specific change plans for the family to implement that week. Finally, children and parents will be brought together to sample a healthy snack or engage in a fun physical activity. During this period parents will practice behavior management skills with their children.

4.2.2 Child Group—Each child session will last 60 minutes (plus 15 minutes with the parents at the end of the meeting). The session will start with an ice breaker activity to get children moving. Fun, educational, hands-on activities will be used to teach children the basics about healthy eating, trying new foods, fun physical activities, and preparing healthy foods using age appropriate activities. Some examples include: (a) the use of colorful, friendly handheld puppets that represent the food groups from the USDA's dietary guidelines; (b) conducting a picture scavenger hunt during which children find pictures of healthy foods from each of the food groups; (c) helping children create their own "healthy plates" using pictures of their favorite healthy foods; (d) arts and crafts activities to demonstrate healthy foods and physical activity; (e) learning songs about healthy foods and physical activity; and (f) having children and parents engage in fruit and vegetable exposure trials. Children also will be involved in helping to prepare and sample healthy snacks.

4.3 Waitlist Control (WLC) Condition

Families assigned to the WLC condition will complete the assessment protocol at baseline, and at 4 and 10 months. After the follow-up period (month 10) families will be invited to participate in the 12-session behavioral family based intervention. No treatment will be delivered until after the 6-month follow-up assessment (month 10), is completed.

4.4 Data Safety Monitoring Plan

A detailed data safety monitoring plan and a data safety monitoring officer will be established to oversee the progress of the project. Adverse events will be recorded by program group leaders and reviewed by the primary investigator and the data safety monitoring officer, and the IRB if necessary. Semi-annual reports detailing participant recruitment, retention, and adverse events will be reviewed and discussed with the data safety monitoring officer.

5. Data Management

The Project Director will be responsible for developing and implementing the computerized database. All staff involved in data collection will be trained and certified in the required

data collection procedures. All computerized data files will be password protected and automatically backed up daily on a central network hard drive.

6. Discussion

The CHIRP Study is a two-arm, pilot randomized controlled trial examining the effectiveness of a behavioral family based intervention on young children's weight status and healthy lifestyle behaviors. Translating research findings into evidence-based public health strategies and clinical practice is one of the greatest challenges in the area of health promotion and disease prevention [47]. This study extends the weight management literature as it is one of the first randomized studies to assess the effectiveness of a community-based weight management intervention for young children living in underserved rural communities.

There are a number of potential and critical challenges we expect to face during this exploratory and developmental study. Designing an intervention that is developmentally appropriate and balancing the burden placed on participating parents is critical to consider. In order to ensure the developmental appropriateness of the intervention our research team includes co-investigators who have extensive experience working with preschool age children in parent training and nutrition programs. Given that preschool age children commonly refuse new foods and parents may handle refusal behaviors in less than optimal ways [48], helping parents develop behavior skills to more appropriately manage child behavior during mealtime is imperative to successfully introduce new healthful foods to young children. Therefore, during our treatment sessions we will discuss parenting strategies, as well as provide numerous opportunities for parents to practice these skills with their child during food exposure trials. Our hands on approach to parent training will allow parents to receive in session feedback from interventionists to learn how to manage child problematic behavior. The parenting components of the intervention will be based on principles from parent-child interaction therapy (PCIT) [49], which was a treatment originally developed to address disruptive behaviors in children 3 to 6 years of age, and for which a co-investigator has expertise.

In addition to developmentally appropriate parent training, the child portion of the behavioral family intervention will be designed to ensure age appropriateness for preschool children. The nutrition and physical activity information presented to children will be done in fun and engaging ways, such as through the use of colorful food puppets that will introduce the MyPlate food groups, pictures, food models, and songs. Fun games, arts and crafts, and physical activities will be utilized to teach children information about healthy lifestyles and facilitate retention of the information. Child group leaders will be trained by our co-investigators with expertise providing nutrition programming to young children to ensure that material and activities are conducted in engaging and interesting ways for preschool age children. To encourage age appropriate modifications to environmental cues in the home, families will be provided with a colorful child portion plate, which will be based on MyPlate recommendations. The plates will encourage parents to offer appropriately portioned foods from the different food groups and promote trying of new foods in children. The developmental appropriateness of the parenting and nutritional information in the BFI will increase the acceptability of the intervention to families and CES administrators.

Self-monitoring of dietary intake and physical activity is a very important behavioral tool that is often difficult for children and families [50]. In our previous trials in rural communities, some families have felt overburdened with monitoring every meal, snack, and drink consumed by their children. In the CHIRP study we hope to decrease the burden

related to monitoring by asking parents to first monitor one meal at a time. For example, families will start with monitoring only breakfast and then later in the program the monitoring of other meals and snacks will be emphasized. In addition, we will problem solve barriers to the monitoring protocol with all families during the review portion of the parent group. Potential solutions will be identified and agreed upon to address identified barriers.

We expect that some families may be disappointed with their assignment to the WLC condition. In addressing the concern of these families, we will first make sure families are aware of this possible treatment assignment during the screening and consenting process. As mentioned previously, we will utilize multiple strategies to retain families in this condition and during the 6 month follow-up period (e.g., payment for assessments, newsletters, birthday cards). Most importantly, we will emphasize that the information from the first groups will be used to develop an enhanced program for WLC families.

One potential limitation of the CHIRP Study is that it consists of only 12 sessions over a 4 month period. This schedule will provide preliminary information about the feasibility of this design, as well as potentially support a full-scale trial with additional intervention and maintenance sessions. However, this 4-month period may not provide sufficient time to build and encourage long-term behavioral and weight status change in young children and their families. Determining the length of treatment is a balancing act between placing additional demands on families and the need for sufficient contact with families to build positive lifestyle changes. This is especially challenging for families in rural counties who often have further to travel for treatment group sessions.

Little is known about potential moderators or mediators of weight status change in preschool age children participating in family based weight management interventions. However, in adolescents participating in weight management programs the family environment has been found as an important mediator for change in weight status [51]. Parents and the family environment may have an even greater impact on weight loss in preschool age children due to the increased role parents play in food selection and preparation. For example, parent and child factors assessed in the CHIRP Study, such as parental feeding practices, child behavioral problems, child mealtime behavior, barriers to participation, and the home food environment may impact the effectiveness of a behavioral family weight management intervention designed for young children and their families. Therefore, a secondary aim of this pilot trial will be to identify and examine potential moderators and mediators of child weight status change.

7. Conclusions

Randomized controlled trials examining the effectiveness of obesity interventions for young children in real-world community-based settings are exceptionally valuable, but too rarely implemented [52]. The CHIRP Study will determine the impact of a community-based intervention delivered to families with young children in rural settings utilizing an existing network, the CES, on child and parent lifestyle behaviors and weight status. In addition, we expect this developmental and exploratory study to provide our team with significant experience to support a larger, full-scale trial examining weight management programs in an important and at-risk population, young children and families from medically underserved rural areas. A full-scale trial will determine whether a community-based intervention delivered to families in rural communities can have positive impacts on child and parent behavior and weight status. The implementation of a behavioral family based intervention with young children and their parents may lead to more improvements in sustainable long-term health behaviors due to unhealthy habits being less firmly established in younger

children. Helping families and young children establish healthier eating and physical activity habits while children are younger has significant implications for preventative health care in medically underserved rural communities. An intervention that impacts the entire family, such as behavioral family based programs, delivered in a respected community organization, may be an acceptable and practical weight management treatment for rural families with young children.

Acknowledgments

The study is supported by a grant from the National Institute for Diabetes and Digestive and Kidney Diseases R21 DK095269.

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Table 1

Schedule of Assessments and Assessment Measures

<i>Measures</i>	<i>Screening/Baseline</i>		<i>Follow-up Assessments</i>	
	Screening	Month 0	Month 4	Month 10
Parent Consent/Child Verbal Assent	X			
Physician Approval Letters Provided/Collected	X			
Personal Demographic Information and Updates	X			
Child Measures				
Medical History Questionnaire/Update	X		X	X
Height/Weight/Waist Circumference	X	X	X	X
Measures to Assess Child Health Behaviors (<i>dietary intake, accelerometry</i>)		X	X	X
Parent Measures				
Medical History Questionnaire/Update	X		X	X
Height/Weight	X	X	X	X
Questionnaires to Assess Parent Health Behaviors and Child/Family Environment (<i>dietary intake, parenting style, feeding environment, home food environment, participant satisfaction</i>)		X	X	X

Table 2

The CHIRP Study Schedule of BFI Session Topics

Session #	BFI Session Topics	
	Parent Group	Child Group
1	Introduction & Modeling	Welcome
2	MyPlate & Monitoring	MyPlate
3	Breakfast & Positive Attention	Breakfast
4	Snack Attack & Stimulus Control	Snacks
5	Beverages and Diary & Commands	Beverages & Diary
6	Lunch/Dinner & Ignoring	Fruits & Vegetables
7	Physical Activity & Contingencies	Get Moving & Screen Time
8	Portion Size	Portion Sizes & Variety
9	Good Night's Sleep	Grains
10	Reducing Screen Time	Proteins
11	Eating Away from Home	Eating While Out and About
12	Long-Term Maintenance	Review