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Sensible Treatment of Obesity in Rural Youth (STORY): Design and Methods

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Abstract

Project STORY is a 3-arm, randomized, planning and feasibility study assessing the effectiveness of two behavioral weight management interventions in an important and at-risk population, overweight children and their parents in medically underserved rural counties.

Participants will include 90 parent-child dyads from rural counties in north central Florida. Families will be randomized to one of three conditions: (a) a Family-Based Behavioral Group Intervention, (b) a Parent-Only Behavioral Group Intervention, and (c) a waitlist control condition. Child and parent participants will be assessed at baseline (month 0), post-treatment (month 4) and follow-up (month 10). Assessment and intervention sessions will be held at Cooperative Extension offices within each local participating 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, self-esteem, body image, and parent BMI.

The goals of the study are to (a) assess the feasibility of recruitment in rural settings, (b) develop and evaluate training protocol for group leaders, (c) determine strategies to increase adherence to monitoring and goal setting protocol, (d) evaluate strategies for participant retention, (e) assess the relative cost-effectiveness of the interventions, (f) assess the acceptability of the intervention to families and Cooperative Extension administrators and personnel, and (g) if successful, estimate the sample size needed for a full scale trial. This research has potential implications for medically underserved rural communities with limited resources and preventive health care services. If successful, a Parent-Only intervention program may provide a cost-effective and practical intervention for families in underserved rural communities.

Keywords

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

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1. Introduction

The rate of childhood obesity is increasing at an alarming rate. Over 37% of children ages 6 to 11 years are either overweight or at-risk for overweight [1], an increase of over 15% from 2001-02 to 2003-04. Childhood obesity has been linked to type 2 diabetes [2,3], insulin resistance and abnormal glucose tolerance [4], and cardiovascular risk factors [5–7]. Obesity-associated annual hospital costs specific to children ages 6 to 17 have increased threefold over the last 20 years [8]. The social and psychological effects of obesity are profound as obese youth are more likely to experience peer victimization, behavior problems, lower self-esteem, and greater body dissatisfaction than their non-overweight peers [9–13].

Children from rural communities are at particular risk for the deleterious, long-term complications associated with obesity. Families from rural areas are one of the largest medically underserved populations in the country. Rural counties have higher rates of poverty [14] and greater percentages of patients with chronic diseases [15]. Rural communities often lack facilities or the environment to promote healthy lifestyles (e.g., playgrounds, walking paths, exercise gyms). Families are also often required to travel longer distances to meet with friends and attend school than their non-rural counterparts. This can make organizing casual play opportunities for children or quick bike rides to a friend's house more difficult. Quality supermarkets and food outlets are also more dispersed. Thus, high quality food products (i.e., fresh fruits and vegetables) can be more expensive or more difficult to obtain for families in rural areas. In addition, the extended distance needed to travel to medical providers also makes it difficult to coordinate family schedules, which ultimately affects all aspects of health care [16]. These factors add an additional level of barriers that make adopting healthier lifestyles challenging for families in rural communities. Nor surprisingly, compared to their urban counterparts, residents in rural areas engage in fewer healthy lifestyle behaviors related to obesity, such as reducing dietary fat intake and decreasing sedentary activities [17]. Consequently, children and adults living in rural communities have higher rates of obesity [18–20].

Venues for establishing health promotion programs for families in rural areas are limited. One alternative is the Cooperative Extension Service (CES) network. Nationally, Cooperative Extension is a partnership between the U.S. Department of Agriculture (USDA) and land-grant universities to ensure that "practical applications of research in agriculture, home economics and rural energy" are provided in every county in the United States. Cooperative Extension programs currently provide services to residents across the U.S. The programs of the Florida Cooperative Extension are generally designed by faculty at the University of Florida in response to community needs as identified by county extension agents and local advisory groups. The CES network offers a unique opportunity in that it provides the infrastructure, stature within rural communities, and knowledge of local communities to support preventive services to families in rural communities.

Behavioral Family-Based interventions including both children and their parent(s) have demonstrated success in producing weight loss in children [21–22]. While the main focus of behavioral family interventions is to impact the child's weight status, these interventions commonly target both the child and parent for weight loss by including both children and parents in group-based intervention sessions. The existing research is limited, however, with respect to its generalizability to diverse community settings. Most weight management trials have consisted of efficacy studies conducted with middle-class participants and delivered in "optimal" (i.e., academic research) venues with a multidisciplinary team of experts, rather than in "real world," community settings.

There is a growing body of research suggesting that working only with the parents(s) to encourage changes in their child's dietary and physical activity patterns may lead to similar or greater weight loss for children than Family-Based interventions that work with parents and children together. [23–24]. Exclusively targeting the parent(s) in behavioral weight loss interventions for children in rural settings may hold several advantages over Family-Based interventions. Given the extended distance needed to travel to providers for families in rural settings, a Parent-Only intervention may make it easier for families to coordinate schedules allowing for better attendance. Parent-Only interventions may also be more cost effective as they require less staff and materials, which is critical for rural communities with limited resources. Unfortunately, only one study to date has published data comparing Family-Based and Parent-Only interventions in a randomized controlled trial. Golan and colleagues reported that children of parents who participated in a Parent-Only intervention targeting weight loss demonstrated greater weight change at post-treatment than children who participated with their parents in the Family-Based intervention program (9.5% vs. 2.4% decrease in percentage overweight) [25]. Like most other trials in this area, this intervention was also conducted in an academic health center. Given the scope and seriousness of obesity in rural America, the lack of intervention studies highlights the pressing need for a clinical trial targeting weight management for children and families in underserved rural settings.

2. Objectives of Project STORY

The primary aim of Project STORY is to evaluate the effects of a Behavioral "Family-Based" intervention and a Behavioral "Parent-Based" intervention, delivered via group contacts to overweight children and/or their parents in rural counties, on children's standardized body mass index. Secondary aims include: (a) examining changes in children's dietary intake, physical activity, self-esteem, and body image, (b) comparing the cost-effectiveness of the Family-Based and Parent-Only interventions, and (c) evaluating the effects of these two interventions on parent body mass index.

The current project is a planning and feasibility study (R34) that, if successful, will provide pilot data to develop and support a grant application for a full-scale demonstration and dissemination trial (R18). The full scale demonstration and dissemination project will build upon the current planning and feasibility study by incorporating: (a) a larger number of participants and rural community intervention sites, (b) incorporation of maintenance sessions, (c) a longer duration of follow-up, (d) the assessment of biological markers of direct relevance to the development of diabetes, diabetic complications, and cardiovascular disease risk factors, and (e) assessment of child physical fitness.

3. Study Design

3.1 Overview

The study sample will include 90 overweight or at-risk for overweight children, ages 8-13 years, and their parent(s) from four medically underserved rural counties in North Central Florida. All participants will receive one of two 4-month lifestyle intervention programs, a Behavioral Family-Based intervention or a Behavioral Parent-Based intervention. Within each county approximately 25 to 30 families will be randomly assigned to one of the two treatment programs or to a waitlist control condition (WLC). The Family-Based intervention condition will include simultaneous, but separate group contacts for both the target child and parent, while the Parent-Only intervention will include group contacts for parents only. Participants in the WLC will complete assessment measures on the same schedule as those in the Family-Based and Parent-Only interventions; they will not receive treatment until completion of the 6-month follow-up assessment. All intervention and follow-up components will be administered via office-based group contacts at the Cooperative Extension office in

participating counties. The protocol for the study was approved by the governing Institutional Review Board.

3.2 Rural Areas

Criteria established by the Office of Management and Budget were used to define rural areas. The OMB categorizes counties based on their population size and integration with large cities [26]. There are five urbanization levels, three for metropolitan counties (i.e., "urban" areas) and two for non-metropolitan counties (i.e., "rural" areas). The rural areas are described as either: (1) a rural county with a city population no larger than 50,000, and (2) a rural area without a city.

3.3 Inclusion Criteria

Children between the ages of 8 and 13 years, with a body mass index 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 within the same dwelling in a rural county that is designated in whole or in part as a "Health Professional Shortage Areas" by the U.S. Department of Health and Human Services [27]. 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 individuals to participate in a weight management program. For families who are not able to access physician care, we will arrange for an appointment with a physician.

3.4 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 musculo-skeletal condition that limits walking; heart condition; chronic lung diseases limiting physical activity; uncontrolled diabetes; 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, or who are currently using prescription weight-loss drugs, insulin, or other diabetic medications will also be excluded from study participation.

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 extension office for intervention sessions, or likely to move out of the county within the next 12 months.

3.5 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 of the parents will consistently attend the program, rather than having parents switch off from week to week. However, as there are many potential barriers to session attendance for families in rural communities, families in which parents are required to rotate attendance on a weekly basis will not be excluded from the study. Siblings will not be allowed to attend treatment group sessions. However, child care services will be available on site for families in both treatment conditions who need assistance in caring for children during group intervention sessions.

3.6 Recruitment and Retention

Recruitment will take place over a 4-month period prior to the beginning of treatment groups in each county. We will recruit and randomize a study sample that broadly represents the population of families with children 8 to 13 years old in rural north central Florida. At least 25% of the sample will be families from racial or ethnic minority groups. Thus we will over-sample racial and ethnic minorities, as approximately 20% of the local community consists of individuals of African-American or Hispanic decent.

Rural communities are often very close-nit and residents can be hesitant to trust individuals from outside the community, especially university researchers who may initially be perceived as more interested in their research than the community. We will work closely with Cooperative Extension personnel as collaborative partners to help build our acceptance within the community. Recruitment will entail direct solicitation methods including direct mailings, distribution of brochures through local schools, newspaper press releases 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 recruiter will make follow-up phone calls to describe the study and to perform a brief phone screen for eligibility. Families that express interest and meet initial eligibility criteria will be scheduled for an in-person screening visit.

Retention of families in weight management interventions trials can be a significant challenge for researchers. We plan a proactive approach to retention during 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 (consistent with treatment assignment) to assist participants in a caring, person-centered manner; (b) making follow-up phone calls immediately after missed sessions and attempting to schedule make-up sessions, (c) allowing staff to negotiate with participants for altered goals (e.g., lower than optimal levels of performance); and (d) providing payment to defray transportation costs ($5 per session). It is expected that this proactive approach will also be helpful in improving adherence to self-monitoring and treatment protocol, ultimately having positive impacts on study outcomes.

The retention of waitlisted participants during the initial intervention, as well as all participants during the 6-month follow-up period, is another specific potential challenge. To help with long-term retention we plan to send out quarterly newsletters counting down the time to the next assessment and the beginning of treatment for waitlist families, as well as birthday cards, to families. For families in the waitlist condition, we will also emphasize the use of information from the first groups to develop an enhanced program for their family. Furthermore, we are compensating families $50 for completing post-treatment and 6-month assessment visits.

3.7 Outcome Measures

Measurements are conducted at baseline, post-treatment (month 4) and at 6-month follow-up (month 10) at the Cooperative Extension office in each participating county. Table 1 contains a schedule of assessment measures administered to participants during the project.

- *Height and weight* will be assessed for both the child and parent. Height without shoes will be measured to the nearest 0.1 centimeter using a Harpendon stadiometer. Weight will be measured to the nearest 0.1 kilogram using a calibrated and certified balance beam scale. Weight will be measured with one layer of clothing on, without shoes, and with pockets emptied.
- *The Youth/Adolescent Food Frequency Questionnaire (YAFFQ)* [28] will be used to assess dietary intake over the preceding month. The YAFFQ will provide an estimate of the child's average dietary intake and corresponding nutritional content (i.e.,

calories, protein, carbohydrates, fat). Parents will be asked to help their children complete the measure.

- *The Self-Administered Physical Activity Checklist (SAPAC)* [29] will be used to assess the child's physical and sedentary activity at each assessment during three days over a one week period (two week days and one weekend day). The SAPAC lists 21 physical activities, with space for listing up to four other activities, and an additional section for reporting sedentary activities. For each assessment time-point, the child will complete one SAPAC during the in-person assessment session by referencing the previous day, then two SAPACs during "typical days" over the next week. The outcome variables utilized will be METS per day, total minutes of physical activity per day, and total minutes of television time per day.
- The *Self-Perception Profile for Children* is a 36-item measures that will be used to measure children's perceptions of self-worth. Specifically, the measure assesses child perception of competence in five specific domains, plus global self-worth [30].
- *The Children's Body Image Scale (CBIS)*[31] will be used to assess body image. The CBIS consists of pictorial scales for boys and girls containing seven body pictures. Children are asked to identify the body figure most like their own (perceived figure) and the body figure they would most like to have (ideal figure). The difference between the ideal and perceived figures is used as the measure of body dissatisfaction.
- *The Children's Eating and Attitudes Test (ChEAT)* [32] is a 26-item questionnaire completed by children that assesses the child's attitudes towards their eating and dietary behavior. The ChEAT is utilized with children as young as 8-years of age. The ChEAT has demonstrated good internal reliability and test-rest reliability.
- *The Child Feeding Questionnaire (CFQ*) [33] is completed by parents. The CFQ is a 20 item measure that assesses the extent to which the parent exerts control over the child's feeding environment. Factor analysis indicates support for the validity of the measure.
- *Program Costs for Cost Effectiveness Analysis* will be calculated by summing the cost of materials and staffing incurred in the delivery of treatment for each group. Materials include treatment manuals, handouts, tracking logs, and miscellaneous costs. Costs of staff time will be measured as compensation paid to them for activities such as training hours and time spent directly working with participants.

3.8 Additional Measures of Treatment Adherence

- Adherence to dietary protocol and goals will be assessed with a seven-day food log, which we refer to as their "habit log". Children and parents will be asked to work together to complete the child's habit log on a daily basis. Parents will also track their personal dietary intake on their own habit log. Children and parents will be trained to complete the daily habit log during the initial group treatment session. Abbreviated habit logs will be available for families who struggle with completing the full monitoring logs. Abbreviated logs will include recording of fruit and vegetables and high fat-high calorie "Red Foods."
- Children and parents will wear a pedometer to track the number of steps they take each day. Steps will be recorded on the daily habit log and average steps per day will be calculated over the course of each week.
- Starting in week 6 of the program, children and parents will also use their habit logs to track time spent watching television and playing video games.

4. Intervention

4.1 Interventionists

The interventions in Project STORY will be delivered by Family and Consumer Sciences (FCS) Agents, in collaboration with a post-doctoral clinical psychologist and graduate students in clinical health psychology. FCS agents have a bachelors or masters degree, often with a concentration in nutrition. FCS agents are typically employed by Cooperative Extension Offices to deliver nutrition education programs. All interventionists for Project STORY will undergo extensive training and certification in the treatment protocols. The PI will conduct periodic direct observation of group sessions to monitor interventionist's performance and assess treatment fidelity. The interventionists will also 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 General Intervention

Parent-child dyads in the Family-Based intervention and parents in the Parent-Only intervention 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 across 16 weeks. All treatment sessions will be conducted at the Cooperative Extension office in the participating counties. For all child and parent participants, the primary treatment objectives will be to build healthier dietary habits, increase moderate intensity physical activity, establish a healthier weight status, and build positive self-worth. Changes in dietary habits will be addressed via a modified version of the Stop-Light Program [34]. Child and parent participants will monitor everything they eat using a daily habit log. Families will have the option of using abbreviated monitoring forms after the first four weeks, or earlier if needed. Goals will be individualized to the needs of each family and based on each individual's baseline dietary intake and progress (i.e., goal attainment, weight change) over the course of the program. Daily dietary goals will be set each week, and will include limiting the consumption of high-fat/high-sugar "red foods" (with an absolute minimum goal of 2 red foods per day), and increasing fruit and vegetable intake. Children and adults will also be encouraged to eat a well-balanced diet based on the food guide pyramid. Although not all parents will have a goal of weight change, it is felt that all parents can benefit from healthier lifestyle habits. Increased physical activity will be encouraged through a pedometer-based step program. Children and parents will be encouraged to monitor their physical activity and gradually increase their steps per day. Program goals will be based on their baseline level of steps and will target an increase of at least 3000 steps/day by the end of the program for both children and parents. This is consistent with literature suggesting overweight children take approximately 3,000 steps per day fewer than their non-overweight peers [35] and is equivalent to an increase of approximately 30 minutes per week of physical activity. Goals will be set for gradually decreasing sedentary activities so that children will spend no more than 2 hours per day watching television or playing video games. If excessive television viewing is not a concern for a given family, group leaders may target non-homework based computer time. Specific behavioral strategies to help families adopt healthier dietary and physical activity habits are outlined in Table 2. Session topics for the 12 intervention sessions are listed in Table 3. Treatment manuals for both child and parent participants, as well as group leaders, have been developed for this project.

4.3 Behavioral Family-Based Intervention

Each parent and child dyad will participate in simultaneous, but separate, parent and child groups. As both children and parents will be targeted as "active agents of change," the emphasis will be on modeling and providing support to work together to establish healthier eating and physical activity patterns. Each session will last 90 minutes. Both children and parents will be weighed every other group session to monitor weight status.

During the parent group, the first portion of the meeting will involve a review of parent and child progress implementing the strategies developed for changing their eating or exercise habits during the previous session. Difficulties reported by the parents will be dealt with through group support and discussion. The second segment will focus on knowledge and skill training related to benefits of weight loss, basics of nutrition and the stoplight program, appropriate methods for increasing physical activity, behavior management, and positive parenting skills (e.g., goal setting, self-monitoring, stimulus control, etc.). At the end of each session, children and parents will be brought together to develop specific goals, as well as plans to achieve these goals.

The child group sessions will include four segments. Each session will begin with a review of the children's progress in completing their monitoring forms and achieving their dietary and physical activity goals. The second segment will use fun and educational activities to teach children about nutrition (e.g., recognizing calorie and fat content of foods via "signals" of the Stop-Light program), strategies to increase physical activity, behavioral management skills (self-monitoring and goal settings), and strategies to cope with psychosocial concerns (i.e., building self-esteem). Third, all sessions will include a physical activity component to demonstrate strategies to help children keep physically active. This will include activities such as jumping rope, playing frisbee, relay races, and participating in a mini-scavenger hunt. Finally, children will help prepare a healthy snack for taste testing during each session.

4.4 Behavioral Parent-Based Intervention

Only the participating parent(s) will attend weekly group meetings. Each session will last 90 minutes and will include three segments, similar to the parent-group previously described in the Family-Based intervention. Each week group interventionists will model the goal setting process with parents and suggest a general range of dietary and physical activity targets that might be appropriate for each child and parent. Parents will then be instructed to meet with their child at home and work together to set individual, achievable goals based on the previous weeks progress. Parents will participate in role-play activities to practice negotiation of goals with their child. *As children will not attend group sessions, an emphasis will be placed on teaching parents how to work with their children to set goals together.* Parents will be encouraged to utilize praise, incentives, and modeling to encourage participation and goal achievement. Parents will be provided handouts to guide them in discussing program material and setting weekly goals with their children. Parents will be weighed every other group session to monitor their weight status.

4.5 Wait List Control 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 a 12-session behavioral-based intervention. No treatment will be delivered until after the final, 6-month follow-up assessment.

5. Data Safety Monitoring Plan

A detailed data and 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.

6. Data Management

The Research Project Coordinator (RPC) will serve as the data manager. The RPC, under the supervision of the statistician and the PI, will be responsible for setting up a computerized database. All staff involved in data collection will be trained and certified in the required data collection procedures, including the anthropometric measures (i.e., height and weight). All computerized data files will be automatically backed up daily on a central network hard drive and will be password protected.

7. Discussion

Project STORY is a three-arm, randomized planning and feasibility study examining the effectiveness of a Family-Based versus Parent-Only behavioral intervention on children's weight status and healthy lifestyle behaviors. The goal of the study, beyond helping participating families in rural communities, is to provide data and information to support a larger, full-scale trail. This study will extend the relevant literature in a number of ways. First, this is one of the first randomized studies to assess the effectiveness of a community-based weight management intervention for children and families in underserved rural settings. The intervention is tailored to meet the needs of families in Southern, rural communities by addressing barriers to physical activity specific to rural children, illustrating low-fat/low calorie food preparation for Southern, rural cooking, and by discussing strategies for eating away from home. To this end, this project utilizes a respected and valued network in rural communities, the Cooperative Extension, to deliver the weight management program to families in their local communities. Finally, this is one of the first randomized studies to compare the effectiveness of Family-Based versus Parent-Only behavioral interventions targeting children for weight management.

There are a number of additional potential and critical challenges that we expect to face during the feasibility study. Adherence to a self-monitoring protocol is a challenge for children and families, even in the best of circumstances. However, adherence to self-monitoring is highly associated with success in child weight management programs [36]. Expecting too much from families may ultimately cause frustration and dropout. To help with adherence to self-monitoring, we initially ask children and parents to monitor everything they eat and drink for the first four weeks of the program using "full" monitoring forms. During week five we switch to abbreviated monitoring forms that we developed for this project. This involves monitoring only the high-fat/high-calorie foods and fruits and vegetables, with different versions including measuring amounts versus just circling if food in a particular category was consumed. However, the abbreviated monitoring forms will be implemented earlier in the protocol as needed based on each family's progress and ability to complete the full monitoring forms.

Children's adherence to wearing pedometers will be another specific challenge. There will be situations when children will not be able to wear their pedometer, such as when they are participating in organized sporting events due to safety concerns (i.e., basketball, football, softball, soccer). Moreover, pedometers do not accurately capture all physical activity (i.e., bicycling, swimming). Thus we will encourage children and parents to record participation in physical activity (time and intensity) during which they are not able to wear their pedometer. In an effort to help with overall adherence to monitoring of physical activity and dietary intake, we will teach parents to use behavior contracts and positive praise to support and motivate children to complete self-monitoring protocol. We will also provide incentives for completing self-monitoring protocol. All children who complete their self-monitoring protocol on 5 of 7 days will be entered into a drawing for a small prize. We realize that this direct reinforcement is only available to children in the family intervention. However, as part of the purpose of this

study is to examine the difference between Family-Based and Parent-Only interventions, we do not expect the direct support from group leaders to children to be equal across groups.

As noted previously, 25% of our participants will be from ethnic minority backgrounds. Unfortunately, recruitment of African American participants for medical research can be difficult [37-38]. We plan to meet with community leaders and secure the endorsement of church pastors to give presentations about the importance of our study to the African-American community at churches predominantly attended by African Americans. This culturally-tailored recruitment strategy has been used effectively in previous trails conducted in our lab with women in rural communities. In addition, we will include "culturally-tailored" features to make the intervention approach comfortable and relevant to African American and Hispanic participants. For example, we will incorporate recipes specially tailored to preferences of different ethnic groups (e.g., the use of the "Down-Home Healthy" eating guide [39], which includes healthy preparation methods for traditional African American foods). Similarly, we have developed a simplified, more user-friendly self-monitoring system using abbreviated monitoring logs and the "stop light" approach.

As census data shows that over 21% of families from participating counties fall below the poverty line, we expect that a significant portion of participating families will be from lower socioeconomic backgrounds. This can have implications on attendance and retention [40-41]. A number of strategies already discussed should help overcome potential barriers to effective interventions associated with lower SES backgrounds. Compensation to defer travel costs, individually tailored treatment goals and plans, and abbreviated monitoring forms should help families with limited financial and educational resources. As financial considerations are also important for families, we have developed an example food budget designed to provide food for a family of four for one week. We will also use the group format to discuss strategies for obtaining and purchasing healthier foods on a limited budget. The group intervention format allows group members to problem solve and share ideas related to overcoming barriers to change. We have found that families are more open to suggestions from other participants, and ultimately provide many wonderful insights to address barriers to lifestyle change.

We expect that some families may be disappointed with their assignment to the Parent-Only condition. In addressing the concern of these families, we will first make sure families are well aware of this possible treatment assignment during the consenting process. During the first group session we will invite parents to discuss the pros and cons of the Parent-Only condition. During this discussion, we will use information gathered during previous groups to emphasize a number of potential benefits, including more experience independently implementing the strategies with their child that may ultimately lead to better long-term maintenance, a calmer and quieter group with time away from the family, and greater ease in coordinating schedules.

One potential limitation is that the current program consists of only 12 sessions over the course of 4 months. However, this schedule should provide preliminary information on the feasibility of this design, supporting a full-scale trial with a longer intervention and maintenance sessions. Regardless, this 4-month period may not provide sufficient time to build and encourage long-term behavioral and weight status change. Determining the length of treatment is a balancing act between placing additional demands on family scheduling and the need for sufficient contact with families to build positive lifestyle changes. This is a special challenge for families in rural counties who often have further to travel for weekly group sessions.

As parent modeling has been shown to have a significant impact on children's dietary intake and physical activity [42–43], parent BMI will be assessed at pre- and post-treatment. However, we will not assess parent dietary intake and physical activity at pre- and post-treatment assessment visits. While we acknowledge that information on parent behavior change would

help further elucidate mechanisms of change for children, we must balance the benefits of collecting such data against the demands placed on participants. The families are asked to complete a number of assessment measures that take approximately 45 minutes, without these parent assessment measures. Thus, we felt adding these additional measures would be too burdensome. We hope to include assessment of parental lifestyle habits in a larger, future trial.

Compared to previous studies using the Stoplight Diet [22,34], the interventions in Project STORY are not setting weekly goals for calorie reduction with child participants. Rather, we encourage children and families to set dietary goals to limit consumption of high-fat/high-sugar "Red Foods" and increase consumption of fruits and vegetables. The feasibility and success of these strategies on weight status change requires careful study and review.

In summary, we expect to gain significant experience from this feasibility study that will ultimately support a larger, full scale trial examining weight management programs in an important and at-risk population, children and families from medically underserved rural areas. A full-scale trial will determine whether a community based intervention delivered to families in rural settings utilizing an existing network such as the Cooperative Extension can have positive impacts on child behavior, weight status and biological markers of diabetes and early cardiovascular disease. This research may have significant implications for medically underserved rural communities where preventive health care services and overall resources are scarce. A cost-effective Parent-Only intervention that impacts the entire family and that is delivered in an existing, respected framework such as the Cooperative Extension Service, may be more cost-effective and practical to implement and sustain over time.

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Table 1

Schedule of Assessments and Assessment Measures

Measure	Screening/Baseline		Follow-up Assessments	
	Pre-Screening	Month 0	Month 4	Month 10
Parent Consent/Child Assent	X			
Physician Approval Letters Provided to Parent/Collected	X			
Personal Demographic Information And Updates	X		X	X
Child Measures				
Medical History Questionnaire/Update	X		X	X
Height/Weight	X	X	X	X
Questionnaire Measures to Assess Child Functioning (Dietary Intake, Physical Activity, Self-Concept, Body Image, and Children's Eating and Attitudes Test (CHEAT)		X	X	X
Parent Measures				
Medical History Questionnaire/Update	X		X	X
Height/Weight	X	X	X	X
Child Feeding Questionnaire (CFQ)		X	X	X
Cost Analysis Information			X	X

Table 2

Behavioral Strategies Utilized in Project STORY

Self-Monitoring	An important self-control technique that involves observing and recording one's behavior. Monitoring is associated with attendance and success in weight management programs [32]. Children and parents will be taught to monitor and record their dietary intake and steps each day.
Goal Setting	Children and parents will be taught the importance of goal setting to facilitate behavior change. Goals will be set on a weekly basis to help modify the intake of high-fat "Red foods", the intake of fruits and vegetables, increase physical activity and decrease sedentary activity. Goals will be tailored to the individual needs of each family.
Shaping	Shaping is a strategy to target gradual changes in behavior to ultimate lyattain a desired goal behavior. This strategy will be implemented by setting weekly goals for gradual change. This is designed to increase self-efficacy and success, and to limit frustration, with the goal of promoting long-term behavior change.
Stimulus Control	Stimulus control is a strategy designed to help participants alter their environment to maximize cues to build positive lifestyle habits/choices and minimize barriers to positive change. Children and parents will be instructed on the principles of stimulus control, as well as specific environmental changes to implement in their home and daily life.
Behavioral Contracting	Behavioral contracting involves developing an agreement by which the child receives specific privileges if they complete a specific task. Parents will be instructed on the use of behavioral contracting and develop specific plans for implementation of a contract.
Contingent Attention	Parents will be encouraged to provide positive attention when children make healthy food and activity choices, but to limit negative interactions when children select sub-optimal dietary and physical activity options.
Positive Reinforcement	Children and parents will be encouraged to provide verbal praise for family members when they make healthy food and activity choices.
Modeling	Modeling is an effective strategy to build healthy lifestyle behaviors in which children learn to emulate their parent's behavior. Parents will be instructed on how their dietary and exercise behaviors, as well as their self-statements, impact their child's attitude and behavior.
Role Playing	Role playing is an effective strategy for facilitating positive interactions and communication. Group sessions with parents will include role play scenarios to practice implementing and communicating strategies with children and other family members.
Incentives	A drawing for a $5 gift card will be held each week in the child group. Children who attended the session will be eligible for the gift card if they complete their monitoring forms.
Portion Size Control	Children and parents will be instructed on the importance of portion control to help limit dietary intake. Specific examples will be reviewed to help participants learn typical and suggested portion sizes for common foods.

Table 3

Schedule of Group Session Topics

Week	Child Sessions	Parent Sessions
1	Self-Monitoring	Self-Monitoring
2	Stoplight Food System	Stoplight Food System
3	Physical Activity	Physical Activity
4	Healthy Eating Patterns &Eating Breakfast	Healthy Eating Patterns &Eating Breakfast
5	Healthy Snacks; Increasing Fruits & Vegetables	Behavioral Strategies for Motivating Your Child; Increasing Fruits & Vegetables
6	Eating Away from Home & Handling Special Occasions; Healthy School Lunch Choices	Eating Away from Home & Handling Special Occasions; Healthy School Lunch Choices
7	Screen Time & Physical Activity; Behavioral Contracts	Screen Time & Physical Activity; Behavioral Contracts
8	Portion Control & The Mealtime Environment	Portion Control, The Mealtime Environment, & Healthy Cooking Strategies
9	Managing Hunger &Emotional Eating	Managing Hunger &Emotional Eating
10	Self-Esteem & Body Image	Self-Esteem & Body Image
11	Handling Teasing &Positive Self-Talk	Handling Teasing &Positive Self-Talk
12	Long-Term Maintenance	Long-Term Maintenance