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The Extension Family Lifestyle Intervention Project (E-FLIP for Kids): Design and Methods

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Abstract

The Extension Family Lifestyle Intervention Project (E-FLIP for Kids) is a three-arm, randomized controlled trial assessing the effectiveness of two behavioral weight management interventions in an important and at-risk population, overweight and obese children and their parents in rural counties.

Participants will include 240 parent-child dyads from nine rural counties in north central Florida. Dyads will be randomized to one of three conditions: (a) a Family-Based Behavioral Group Intervention, (b) a Parent-Only Behavioral Group Intervention, and (c) an Education Control Condition. Child and parent participants will be assessed at baseline (month 0), post-treatment (month 12) and follow-up (month 24). Assessment and intervention sessions will be held at Cooperative Extension Service offices within each participating county. The primary outcome measure is change in child BMI z-score. Additional key outcome measures include child body fat, waist circumference, dietary intake, physical activity, blood lipids, blood glucose, blood pressure, physical fitness, quality of life, and program and participants costs. Parent BMI, dietary intake, and physical activity also will be assessed.

Randomized controlled trials testing the effectiveness of childhood obesity interventions in real-world community-based settings are extremely valuable, but much too rare. The E-FLIP for Kids trial will evaluate the impact of a community based intervention delivered to families in rural settings utilizing the existing Cooperative Extension Service network on long-term child behavior, weight status and biological markers of diabetes and early cardiovascular disease. If successful, a Parent-Only intervention program may provide a cost-effective and practical intervention for families in underserved rural communities.

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Keywords

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

1. Introduction

Childhood and adult obesity are associated with alarming health consequences [1-6]. Not only does obesity exact a toll in terms of morbidity and mortality, but it also has substantial economic and psychosocial effects. The total economic costs related to obesity exceed \$117 billion and obesity-associated annual hospital costs specific to children ages 6 to 17 have increased threefold over the last 20 years [7]. The social and psychological effects of obesity on children can be profound and include social discrimination and decreased emotional well-being [8-11].

Improvements in weight status for youth who are obese can lead to significant health benefits [12,13]. Family-based behavioral interventions have demonstrated success in producing weight loss in children [14]. However, much of the existing research in this area cannot be generalized to diverse community settings as most intervention trials have consisted of efficacy studies conducted with middle-class, metropolitan families and delivered in “optimal” academic research venues. One of the greatest challenges facing health promotion is translating research findings from efficacy studies into evidence-based public health and community settings [15]. Randomized controlled trials testing the effectiveness of childhood obesity interventions in real-world community-based settings are extremely valuable as they bridge this gap. Unfortunately, they are much too rare [16].

Twenty percent of the United States population lives in rural areas, but rural areas account for 75% of the medically underserved areas in the U.S. Children living in rural areas are 25% more likely to be overweight or obese than their peers living in metropolitan areas [17]. Rural counties have higher rates of poverty [18] and greater percentages of patients with chronic diseases [19]. Rural communities often lack facilities or the environment to promote healthy lifestyles (e.g., playgrounds, walking paths, exercise gyms). The level of resources needed to deliver effective interventions, as well as the limited access to health promotion programs, represent significant barriers to dissemination into rural community settings.

Developing and evaluating cost-effective interventions that positively impact children’s long-term weight status and related health parameters are critical to promoting improved health of youth, especially in underserved rural settings. Unfortunately, little research attention has focused on strategies to address this disparity. Our team recently completed a pilot lifestyle intervention program delivered through Cooperative Extension Service offices in rural communities that was funded by National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK) via a Planning Grant for Translational Research. Outcome data suggest that a parent-only intervention that includes only parents in treatment groups may be a feasible, cost-effective and sustainable alternative intervention to family-based programs that include both the child and parent in medically underserved rural settings [20,21]. However, additional research to replicate these findings that includes long-term follow-up and assessment of biological outcome markers is needed before drawing definitive conclusions.

2. Objectives of the E-FLIP for Kids Project

The E-FLIP for Kids study is funded by grant from NIDDK for Translational Research for the Prevention and Control of Diabetes and Obesity (R18). The study builds upon our pilot

study [20,21] also funded by NIDDK by expanding the number of participants and rural community intervention sites and including maintenance sessions up to one year, follow-up at two years post-baseline assessment, and greater breadth in the assessment of relevant outcome variables. The primary aim of the study is to evaluate the effects of a Behavioral “Family-Based” intervention and a Behavioral “Parent-Based” intervention relative to an education control condition, delivered via group contacts to overweight and obese children and/or their parents in rural counties, on children’s standardized body mass index. The study was powered for two primary comparisons, both at 24-month follow-up: the Behavioral Family-Based Intervention versus the Education Control, and the Behavioral Parent Only Intervention versus the Education Control. Secondary aims include: (a) examining changes in children’s dietary intake, physical activity, body fat, waist circumference, blood pressure, lipids, glucose, and physical fitness, (b) comparing the cost-effectiveness of the Family-Based and Parent-Only interventions, and (c) evaluating the effects of these two interventions on parent weight, dietary intake and physical activity. Our overarching goal is the development of a lifestyle intervention with the potential for positive long-term effects on child health and dissemination into community settings.

3. Study Design

3.1 Overview

The study sample will include 240 overweight or obese children, ages 8-12 years, and their parent(s) from nine medically-underserved rural counties in North Central Florida. Participants will be treated in three successive cohorts consisting of approximately 80 child-parent dyads across three counties per cohort. Within each county approximately 25 to 30 families will be randomly assigned based on availability to one of three 12-month intervention programs, a Family-Based Behavioral lifestyle intervention, a Parent-Only Behavioral lifestyle intervention, or a Family-Based Education control condition. The Family-Based interventions 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. At least 25% of the sample will be families from racial or ethnic minority groups. 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 (OMB) were used to define rural areas. The OMB categorizes counties based on their population size and integration with large cities [22]. 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, or (2) a rural area without a city.

3.3 Cooperative Extension Service

Venues for establishing health promotion programs for families in rural areas are limited. One alternative is the Cooperative Extension Service (CES) network. Nationally, the CES is a partnership between the U.S. Department of Agriculture (USDA), land-grant universities, and county governments to ensure that useful, practical, and research-based information is provided to agricultural producers, small business owners, youth, consumers, and others in rural areas and communities of all sizes. CES programs currently provide educational programs and information related to agriculture, natural resources, family and consumer sciences, and youth development to residents across the U.S. The CES network offers a unique opportunity in that it provides the infrastructure, the link to the resources of the land-grant universities in each state, stature within rural communities, and knowledge of local

communities to support prevention programming to families in rural communities. All intervention and follow-up components will be administered via office-based contacts at the CES office in participating counties.

3.4 Inclusion Criteria

Children between the ages of 8 and 12 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 within the same dwelling in a rural county. Participating parents or legal guardians must be age 75 years or less.

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 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, antibiotics for HIV or tuberculosis, chemotherapeutic drugs or 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 the initial in-person screening visit. Families will be excluded if the child has a resting blood pressure $\geq 140/90$ mm Hg.

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 Extension office for intervention sessions, or likely to move out of the county within the next 24 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 of the parents will consistently attend the program, rather than having parents switch off from week to week. Siblings will not be allowed to attend treatment group sessions; however, child care services will be available on-site for families in all three treatment conditions who need assistance in caring for 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 8 to 12 years old in rural north central Florida. Treatment groups within each county will occur on separate weeknights (Monday, Tuesday, Wednesday, or Thursday). Rural communities often are very close-knit and residents can be hesitant to trust individuals from outside the community. We will work closely with CES 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, distribution of brochures to 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 in-person 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 below in section 3.9. Families will be notified of their assignment to treatment condition at the end of the baseline assessment visit.

Retention of families in weight management interventions trials can be a significant challenge for researchers. Similar to our pilot study [21], 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); (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; (d) having abbreviated monitoring forms for families that struggle with monitoring everything they eat on a daily basis; 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 self-monitoring and the treatment protocol, ultimately having positive impacts on participant attendance, retention, and study outcomes. Furthermore, families will receive \$50 for completing the post-treatment (month 12) assessment and an additional \$50 for completing the one-year follow-up (month 24) assessment.

3.8 Randomization

Within each county, recruitment will continue until 25-27 families are ready to proceed to randomization. The protocol will randomly assign 8 to 9 families to each of three weeknight intervention groups. We will employ a replicated Latin square design, with treatment numbers arranged accordingly. This design explicitly accounts for two sources of variation by simultaneously blocking on two factors. However, the number of levels of each blocking factor must be equal to the number of treatments. For E-FLIP for Kids, time of treatment (which weeknight) and county within cohort are the blocking factors. Thus, within each cohort, the rows (three counties) and then the columns (three weeknights) will be randomly permuted, and then the three treatment conditions will be assigned randomly to the treatment numbers. This process will be repeated for each Latin square (cohort). Assignment of treatment condition to weeknight based on the Latin squares will be completed by our study statistician, who will have no contact with families or baseline assessment data.

It would be ideal if each child-parent dyad would be available to be randomized to each of the three evenings on which treatment groups were scheduled in their respective county. However, many families have busy schedules and do not have three “open nights” in their weekly calendar. Thus, we felt recruitment would be substantially hindered if we made this a requirement for study participation. As such, we will ask families to inform us which evening(s) they could be available to participate in a group treatment. Families will then be randomized to weeknight based on availability, so that 8 to 10 families are assigned to each of the three weeknights in each county. Randomization of treatment condition to specific weekday evening in each county will be blind to families and assessment personnel.

3.9 Assessment and Outcome Measures

Measurements are conducted at baseline, post-treatment (month 12) and at one-year follow-up (month 24) at the CES office in each participating county. Table 1 contains a schedule of

assessment measures administered to participants during the project. All questionnaires were written at the 5th grade reading level.

- *Medical history and current medication* use for both the child and parent will be gathered via parent report at each assessment. At 12-month and 24-month assessments this will also include assessment of child and parent medication use at any point during the 12 months since the preceding assessment.
- *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 digital scale. Weight will be measured with one layer of clothing on, without shoes, and with pockets emptied.
- *Child Dietary Intake* will be assessed using the Block Kids 2004. This is a 77-item questionnaire that assesses children's dietary intake over the past month [23]. The food list for this questionnaire was developed from the NHANES 1999-2002 dietary recall data. The nutrient database was developed from the USDA Nutrient Database for Dietary Studies, version 1.0.
- *Child Physical Activity and Energy Expenditure* will be assessed via the Sensewear Armband Accelerometer. Children will be instructed to wear the accelerometer for seven consecutive days, 24 hours per day, (except when bathing or swimming). The Sensewear armband technology (Bodymedia, Inc., Pittsburgh, PA) provides an objective assessment of total and physical activity energy expenditure [24,25].
- *Resting Heart Rate and Blood Pressure* will also be assessed for each child. The child will be seated, with feet resting on the floor, for five minutes in a quiet room free of distractions. Resting heart rate and resting systolic and diastolic blood pressure will then be taken using a manual blood pressure cuff while the child is seated and resting comfortably.
- *Child Blood Analyses*. Under aseptic conditions, using standard procedures, approximately 1 ml of blood will be collected via finger prick and analyzed for glycosylated hemoglobin, total cholesterol, and HDL-cholesterol by using GDX and LDX Cholestech point-of-care devices (POCD) [26,27].
- *Child Body Fat Percentage* will be assessed via the Tanita BC-533 bioelectrical impedance scale. The Tanita BC-533 was created for use with children 7 to 17 years of age and has a child specific mode, which takes into account child's weight, height, age, and gender to ensure accurate measurements. The Tanita BC-533 has been shown to be safe and effective and has been used in previous research examining body fat percentage in youth [28].
- *Child Cardio Respiratory Fitness* will be assessed via the Progressive Aerobic Cardiovascular Endurance Run (PACER) [29]. The PACER is a multistage test adapted from the 20-meter shuttle run test [30,31] that is widely accepted as a valid estimate of cardio respiratory fitness outside of a laboratory. To conduct the PACER test at the various CES sites, a 20-meter distance will be marked in which there are no physical obstacles or pedestrian traffic. The PACER test involves running back and forth across this 20-meter course in time to music played from a CD. Beeps on the sound track indicate when the child should reach the end of the course.
- *Child Health-Related Quality of Life* will be assessed via the Pediatric Quality of Life Inventory (PedsQL). The PedsQL is a 23-item scale that measures health-related quality of life in healthy children and those with acute and chronic

conditions. The measure has been reported to have excellent internal consistency, clinical validity, and factor-analytic support for subscales [32]. There are both child and parent report forms; both will be completed in this study.

- *Child Disordered Eating Attitudes and Behaviors* will be assessed via the 26-item Children's Eating Attitudes Test (ChEAT). The ChEAT has been reported to have good internal reliability and concurrent validity with measures of body dissatisfaction and weight control behaviors [33].
- *Child Social Skills* will be assessed via the Social Skills Improvement System (SSiS). The SSiS is a 75-item self-report measure created for children 8 to 12 years of age. Items are rated on a four-point likert scale with higher scores indicating more appropriate social skills [34].
- *Child Body Image* will be assessed via the Children's Body Image Scale (CBIS). The CBIS is a self-report measure that consists of seven silhouettes of male or female youth that correspond to increasing weight status. 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). Body dissatisfaction is calculated as the absolute value of the difference between the perceived and ideal figures selected [35].
- *Parent Dietary Intake* will be assessed with the Block Brief 2000 Food Frequency Questionnaire. 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 [36].
- *Parent Physical Activity* will be assessed via the Block Physical Activity Screener [37]. This is a brief screening tool that contains 11 items, including job-related, daily life, and leisure activities. It asks about frequency and duration of these activities during the past year. The physical activity items were identified using the National Human Activities Patterns Survey data, and quantified using the Ainsworth Compendium.
- *The Child Feeding Questionnaire (CFQ)* 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 [38].
- *Parent-Child Communication and Conflict* will be assessed via the Conflict Behavior Questionnaire (CBQ-20). The CBQ-20 assesses parent-child conflict, arguments, and disagreements over the past two weeks via a 20-item true or false scale. The parent report version will be used in this study. The CBQ-20 has been used extensively throughout the literature and has adequate internal consistency [39].
- *Parent Problem-Solving Skills* will be assessed via the Social Problem Solving Inventory-Revised (SPSI-R). The SPSI-R is a 52-item measure yielding five subscales. The five factors are: positive problem orientation, negative problem orientation, rational problem solving, impulsivity/careless style, and avoidance style. The first two factors represent "problem orientation," and the latter three represent "problem solving style." Three-week test-retest reliability coefficients for the SPSI-R subscales range from .72 to .88 [40].
- *Pubertal Development* will be assessed via the Pubertal Development Scale (PDS) [41]. The PDS is a five to six item measure (five for boys, six for girls) that will be

used to assess pubertal development in child participants. The measure provides a continuous score of pubertal development and change. The measure has acceptable psychometric properties.

- *Analysis of Costs and Cost Effectiveness Analysis.* Comparison of costs across the various conditions will be based on average costs per family in each group. Costs will be divided into direct and indirect costs and further divided into those borne by the program and those incurred by study families. The fixed direct start-up costs for all conditions will involve training and setting up resources for staff to conduct the programs. Direct program costs after start-up include: resources required for meetings, staff preparation, meeting time, and materials for participants. Overhead and administrative costs will be allocated to intervention condition based on the use of resources (e.g., office space). Although program costs will be the primary factor in determining the relative costs for each group, the costs of participation will also vary and will require consideration for a complete analysis of costs and cost-effectiveness. For the three intervention conditions, per-session participation costs will be similar and include the value of parent time spent in the educational sessions, as well as time spent outside of the sessions engaged in exercise and diet modification activities. For the control condition, only time spent in the educational sessions will be monitored, as no outside lifestyle modification program is proposed for this group of participants. Family costs will also include both travel distance and time to participate in the sessions, as well as costs for babysitting. To assess cost-effectiveness, we will first calculate the average effectiveness of each intervention program (BFI and PO) in terms of (1) change in standardized BMI for children, and (2) weight loss for adults at month 24. We will rank the programs according to effectiveness from least to most (highest to lowest change in BMIz and weight). This will result in two comparisons of incremental CE ratios; the first would determine the average cost differential between the programs for children, and the second for adults. This will become the denominator for the CE ratio. The numerator for the ratio will be the average total program costs (direct + indirect) at month 24.

3.10 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 the participant's "habit log." Children and parents in the two Behavioral Interventions 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 fruits and vegetables and high-fat/high calorie "Red Foods." In subsequent weeks children and parents will also use their habit logs to track fruit and vegetable intake, as well as time spent watching television and playing video games.

Children and parents in the two Behavior Interventions 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.

3.11 Medical Referral Following Screening

When a participant is identified at screening or assessment as experiencing a significant health issue, the study nurse will send the parent a letter describing our findings and encouraging them to consult with their physician. The nurse will also make a follow-up phone call to the parent to answer questions and again encourage them to share this

information with their physician. If this family does not have a physician we will make an appropriate medical referral.

4. Interventions

4.1 Interventionists

The interventions in the E-FLIP for Kids program 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 and typically have a Bachelors or Masters degree. All interventionists for E-FLIP for Kids will undergo extensive training in the treatment protocols. Sessions will be recorded via audio tape to allow the 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 General Intervention

The Family-Based Intervention and Parent-Only Intervention will involve a fading level of contact over a 12-month period. Child-parent dyads in the Family-Based Intervention, and parents in the Parent-Only Intervention, will attend weekly group sessions for the first eight weeks, then four biweekly sessions over the next eight weeks for a total of 12 sessions across 16 weeks. Contact will then fade to one group session per month for months 5-12, with the exception of month 9, during which participants will attend two group sessions. Each session will last 90 minutes.

All treatment sessions will be conducted at the CES 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 Eating Plan [42]. 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 of self-monitoring, 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-calorie "red foods" (with an absolute minimum goal of two 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 USDA's MyPyramid food guide.

Children and parents also will be encouraged to set weekly physical activity goals beginning in week three. Children and parents will be encouraged to monitor their steps via a pedometer, as well as other non-step activities (riding a bike, swimming, skate boarding) via their weekly habit log. 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 [43] or to increase moderate to vigorous physical activity by 30 minutes per day. Goals will also be set for gradually decreasing sedentary activities so that children will spend no more than two 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. Treatment manuals for participants and group leaders have been developed for this project.

4.3 Family-Based Behavioral Intervention

Children and parents will meet in simultaneous, but separate, parent and child groups at each meeting. 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. Parents will discuss with group leaders the successes, challenges, and barriers encountered as they attempted to make lifestyle changes since the previous sessions, as well as discuss possible strategies for overcoming various challenges. Good progress will be highlighted by strong positive feedback. Difficulties reported by the parents will be dealt with through group support and advice. The second segment of the session will focus on the specific “topic of the day”. This will involve knowledge and skill training related to the stoplight eating plan, basics of energy balance and nutrition, appropriate methods for increasing physical activity, establishing health eating patterns, proper portion size for foods, healthy cooking strategies, meal planning on a limited budget, eating healthy when eating out, improving self-esteem and body image, behavior management, and positive parenting skills (e.g., goal setting, self-monitoring, stimulus control, etc.). The third segment will involve bringing children and parents back together at the end of each session to set specific goals to work towards for the next session.

The child group will start with a review of the children’s progress in achieving their dietary and physical activity goals over the previous week. Good progress will be highlighted by strong positive feedback. Children will then participate in an exercise or game component to demonstrate strategies/activities to help children keep physically active including activities such as frisbee, flashlight tag, watermelon relay, jump rope, kickball and dancing. Third, children and group leaders will prepare and sample a healthy snack such as fruits and vegetables with various healthy low-fat dips, bagels with low fat cream cheese, low fat cheese quesadillas, fruit smoothies, and yogurt fruit parfaits. During the food sampling portion of each session, fun and educational activities will be used to teach children about nutrition (e.g., recognizing calorie and fat content of foods via “signals” of the Stoplight plan), strategies to increase physical activity, behavioral management skills (self-monitoring and goal setting), and strategies to cope with psychosocial concerns (e.g., building self-esteem, being a good friend) and how to also support their parents. Finally children will join their parents to set lifestyle behavior goals. Parent will not participate in group physical activities during the group meeting.

4.4 Parent-Based Behavioral Intervention

Only the participating parent(s) will attend weekly group meetings. The structure and content of the group will be identical to the parent-group previously described in the Family-Based Behavioral Intervention except that children will not be present to set goals with their parents. Rather, parents will be instructed to meet with their children at home and work together to set individual, achievable goals based on their previous progress. 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. 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 participate in role-play activities as needed to practice negotiation of goals with their child. Parents will be encouraged to utilize praise, incentives, and modeling to encourage participation and goal achievement. Parents will be given handouts to guide them in discussing program material and encouraged to discuss with the group any potential barriers they may encounter when implementing the program with their children. Parent will not participate in group physical activities during the group meeting.

4.5 Family-Based Education Control Condition

Both the child and parent will attend the treatment sessions in this condition, which will include 21 group meetings on the same schedule as the previously described behavioral interventions. Each session will last 90 minutes. The Health Education condition will include a series of meetings addressing key aspects of nutrition, physical activity, and health promotion. The health education curriculum will include topics such as national guidelines regarding proper nutrition, guidelines for physical activity, healthy sources and guidelines for intake of fiber, calcium, protein, grains and carbohydrates. Topics will also include the use of vitamin and mineral supplements, dental and sleep hygiene, self-esteem, family communication, and assertiveness training in dealing with peer victimization. The families in the Health Education group will not receive training in behavioral self-regulation strategies, such as goal setting and self-monitoring. There will be no instruction on behavioral parenting strategies and parent modeling. Children will participate in a group physical activity during each session such as frisbee, jump rope, and tag. They also will sample healthy snacks such as pretzels, fruits and vegetables. There will be no discussion of implementing these activities and preparing healthy snacks in other settings. Parent will not participate in group physical activities during the group meeting.

It is possible that some of these families will learn about behavior change strategies through sources outside our group intervention and subsequently use these strategies to help encourage behavior change. Thus, parents in this condition will complete a brief questionnaire at 12- and 24-month follow-up to ascertain if they utilized any behavioral strategies to encourage lifestyle change, and the frequency with which these were used.

4.6 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 Data Manager, under the supervision of the statistician and the PI, 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, 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.

6. Discussion

The E-FLIP for Kids study is a three-arm, randomized controlled trial examining the effectiveness of Family-Based and Parent-Only Behavioral Interventions on children's weight status and healthy lifestyle behaviors. One of the greatest challenges facing health promotion and disease prevention is translating research findings into evidence-based public health strategies and clinical practices that are actively disseminated and widely adopted [15]. The E-FLIP for Kids study extends the literature in this area as it is one of the first randomized studies to assess the long-term effectiveness of a community-based weight management intervention for children and families delivered in real-world rural settings.

In the context of pediatric obesity treatment, there are two significant barriers to research translation and dissemination in underserved rural settings. The first is the lack of an infrastructure to offer a venue and providers whereby families might have access to treatment. To this end, this project utilizes a respected and valued educational network in rural communities, the CES, to deliver the weight management program to families in their local communities. The CES, with offices in over 3000 counties across the United States, may be an ideal venue for disseminating, implementing, and sustaining lifestyle interventions to families in rural areas. The second barrier is limited financial resources. Our previous work suggested that a Parent-Only Behavioral weight management intervention delivered in CES offices may be a cost-effective alternative to Family-Based Behavioral interventions for overweight and obese children and their families. However there were some important limitations in our pilot study. The E-FLIP for Kids Trial will extend our previous work in five critical ways by including: (a) more treatment contacts over a longer period of time, allowing for both greater initial weight status change and building strategies to assist in maintenance of gains; (b) collection of long-term follow-up data at 24 months; (c) assessment of changes in key biological outcomes to assess clinical significance of potential improvements in weight status; (d) accelerometry to assess changes in physical activity and energy expenditure; and (e) a more comprehensive assessment of parent outcomes.

In the broader context of health promotion, a significant limitation of the health promotion research base is the limited attention to external validity, which is critical when evaluating the potential for dissemination of interventions [44]. The E-FLIP for Kids trial includes a number of design elements that can help maximize external validity [45]. Not only is the intervention conducted in a community setting, but the interventionists have diverse educational backgrounds (i.e., psychology, nutrition, education) and include both faculty from our community partners (the CES offices) and members of our research team. Eligibility criteria are broad so that our sample is not narrowly defined. The study design uses a number of strategies to recruit and retain a representative and diverse sample of the population including mailers, distribution of brochures at schools, and distribution of brochures and flyers at physician offices. We will also meet with community leaders and church pastors from racial and ethnic minority groups to secure their endorsement about the importance of our study and then gave presentations at churches and various community events. The intervention is designed to be flexible, so it can meet the needs of individual families. For example, the monitoring forms and order of session topics can be modified to meet the most pressing needs of treatment group members. We will assess on program costs, quality of life, and potential negative outcomes of the intervention (e.g., the development of unhealthy eating attitudes and behaviors) that will allow for a broader assessment of “program success.” Finally, we will assess a variety of moderating and mediator variables that theoretically may impact treatment outcomes including socio-economic status, family problem solving skills and communication, child social skills, parent control of the feeding environment, and adherence to self-monitoring protocols, and treatment fidelity.

There are some important potential challenges that may arise during this randomized controlled trial. Self-monitoring of dietary intake and physical activity is a critical behavioral tool that is often challenging for children and families [46]. We attempt to problem solve barriers to monitoring protocol with all families; however, our experience has been that for some families the demand is too much. Thus, we have developed abbreviated monitoring forms that involve recording only “Red foods” and fruits and vegetables. We offer all families the choice to switch to the abbreviated forms during week five, or earlier if families struggle with completing the full monitoring forms.

An additional challenge is the training of interventionists with diverse educational backgrounds and intervention experience. While CES faculty often have significant experience with nutrition education programming and rural communities, they have less experience with other intervention components including group processing, behavior parent training, goal setting, and problem solving. To facilitate this training, CES faculty that participated in our previous pilot study helped update the intervention manuals and protocol, as well as the group leader training protocol for the current trial. Moreover, all interventionists will participate in multiple training sessions and weekly supervision phone calls with the project director.

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 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 their treatment condition. During this discussion, we will use information gathered during our pilot study to emphasize potential benefits, including more experience independently implementing the strategies with their child that may ultimately lead to better long-term maintenance. Parents who attended the parent-only condition in our previous trial expressed significant satisfaction with the program, with many parents noting the groups were “their time to get away.”

7. Conclusions

Randomized controlled trials testing the effectiveness of childhood obesity interventions in real-world community-based settings are extremely valuable, but too rarely implemented [16]. The E-FLIP for Kids trial will determine the impact of a community-based intervention delivered to families in rural settings utilizing an existing network, the CES, on long-term child behavior, weight status and biological markers of diabetes and early cardiovascular disease. If both the Parent-Only and Family-Based Behavioral interventions lead to greater decreases in long-term child weight status than the control condition, the results may have significant implications for the treatment of obesity in medically underserved rural communities where preventive health care services and overall resources are limited. This research may help identify a cost-efficient and effective alternative to Family-Based interventions for pediatric obesity that can still impact the entire family.

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Table 1

Schedule of Assessments and Assessment Measures.

Measure	Screening/Baseline		Follow-up Assessments	
	Pre-Screening	Month 0 (Baseline)	Month 12	Month 24
Parent Consent/Child Assent	X			
Personal Demographic Information and Updates	X		X	X
Child Measures				
Medical History Questionnaire/Update	X		X	X
Height/Weight	X	X	X	X
Other Anthropometric Measures (<i>Body Fat, Waist Circumference</i>)		X	X	X
Measures to Assess Child Health Behaviors and Psychosocial Functioning (<i>Dietary Intake, Accelerometry, Cardio Respiratory Fitness, Body Image, QOL, and Children's Eating and Attitudes Test, Social Skills Inventory, Participant Satisfaction</i>)		X	X	X
Biological Markers of Disease (<i>Child resting heart rate, blood pressure, glucose and lipids</i>)		X	X	X
Parent Measures				
Medical History Questionnaire/Update	X		X	X
Height/Weight	X	X	X	X
Questionnaires Assessing Parent Dietary Intake and Physical Activity		X	X	X
Measures to Assess Child and Family Environment (<i>Child Feeding Questionnaire, Pubertal Development Scale, Problem Solving Inventory, Parent-Child Communication, Participant Satisfaction, program costs</i>)		X	X	X