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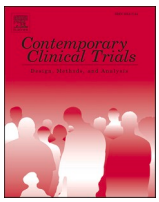

Rationale and design of integrating a parents first obesity intervention with a pediatric weight management intervention for rural families – Evaluating the ripple effect

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ABSTRACT

Rural families are disproportionately affected by obesity. Obesity often runs in families and is impacted by hereditary components, the shared home environment, and parent modeling/child observational learning. Moreover, parent changes in weight predict child changes in weight. Thus, targeting the family unit has the potential to enhance outcomes for adults and children simultaneously. Additionally, engaging rural nurses in medical clinics and schools may be important in determining whether rural telehealth programs are successfully implemented and sustained. This paper describes the rationale and design of a randomized control trial (RCT) evaluating the effectiveness of an integrated adult- and child-focused obesity treatment tailored for rural participants. Outcomes of this study include participant weight loss from baseline to 9-months, device-measured physical activity, and dietary intake. This project will additionally compare reach between clinic and school settings and evaluate the impact of nurse engagement. This study will include 240 participants from eight rural communities who will be randomized to either a Parent +Family-based group or a Newsletter +Family-based group. Parents in the Parent +Family-based group will receive a 3-month adult obesity treatment designed for adult behavior change as a first step. Then, parents and children together will enter the family-based program (iAmHealthy), allowing for potential enhancement of a theorized ripple effect. Parents in the Newsletter +Family-based group will receive 3 monthly newsletters and then participate in the 6-month family-based intervention designed for child behavior change. This study is the first RCT to examine the effectiveness of an integrated adult- and child-focused obesity treatment program.

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1. Introduction

Both children [1] and adults [2] in rural areas have higher obesity rates than their urban counterparts. With less access to evidence-based interventions, obesity poses a major risk factor, contributing to elevated morbidity and mortality from cardiovascular disease, diabetes, and cancer among rural Americans [3]. Obesity runs in families and having a parent with overweight/obesity more than doubles the risk for child overweight/obesity [4]. The familial trait of obesity has been linked to a multitude of factors including hereditary components [5,6], shared home and family environment (e.g., family diet, activity, and screen time patterns) [7], and parent modeling/child observational learning [8]. Moreover, parent changes in weight, diet, and physical activity predicts child changes in weight, diet, and physical activity

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[9–12]. Thus, targeting the rural family unit has the potential to enhance outcomes for adults and children simultaneously.

Family-based behavioral group (FBBG) treatments allow for a single provider to treat multiple families in a single one-hour session and are the gold standard for pediatric obesity treatment [13]. Two defining features of FBBG interventions are the involvement of parents in treatment and the use of cognitive-behavioral techniques such as goal setting, self-monitoring, positive reinforcement, and stimulus control. While FBBGs typically focus on both parent and child weight related behaviors, these interventions have attempted to make changes concurrently rather than consecutively. It is potentially difficult for parents to adequately focus on making notable changes in their own health goals while also trying to monitor and help change child health behaviors.

Conversely, adult-only obesity treatment programs fail to address the unique needs of parents with elementary age children, and there is little information on the role that children play on parent outcomes. The transition to parenthood is associated with decreased physical activity [14], increased unhealthy eating [15], and weight gain over time [16], and this "child effect" may be sustained throughout child-rearing years [16,17]. Factors contributing to the "child effect" may include greater stress, time-related barriers, and changes in the home food environment and family meals [18–20]. Despite this, there have been very few adult health behavior/weight loss studies targeted for parents, and these have been limited to parents with infant to preschool age children [21]. An adult behavioral weight loss trial found that participants with children age 18 and under lose significantly less weight compared to participants without children or whose children were over age 18 [22,23]. To our knowledge, no prior adult studies have been targeted to the unique needs of parents with elementary-aged children. One potential approach to improve the health of the entire family unit would be to begin with an efficacious adult-focused behavioral intervention targeted to the needs of parents with elementary-aged children prior to an FBBG focusing on the health of the child/entire family. Beginning with an adult-focused intervention may have a "ripple effect" [24] resulting in greater improvements in the child.

Participant reach (the proportion and representativeness of those who participate) [25] of behavioral obesity treatment is particularly important in rural communities where smaller population sizes may require a higher participation rate to sustain a program. Engaging rural nurses in medical clinics and schools may be particularly important in determining whether rural telehealth programs are successfully implemented and sustained [26]. Exploring the effects of local nurse engagement on reach across school and clinic settings may have novel and important implications for program reach and sustainability.

The purpose of this paper is to describe the design of an integrated adult- and child-focused obesity treatment approach in an adapted intervention tailored for rural participants.

2. Study design

2.1. Overview

Participants from eight rural communities will be randomized to either a Parent+Family-based group or a parent Newsletter+Family-based group. Parents in the Parent+Family-based group will receive a 3-month proven adult obesity treatment program (modeled after the national Diabetes Prevention Program [27] and the Look AHEAD Lifestyle Intervention [28]) designed for adult behavior change as a first step. Then, parents and children together will enter the family-based program (iAmHealthy), allowing for potential enhancement of the theorized "ripple effect." Both arms will receive the 6-month family-based intervention designed for child behavior change. The primary outcome of this study is participant weight loss from baseline to 9-months. Fig. 1 displays the study flow diagram. This study initially included different assessments (e.g., ActiGraphs) and an additional one year follow up that were cut due to budget constraints. This study has been approved by the University of Kansas Medical Center Institution Review Board (IRB).

Note. Fig. 1 displays the study flow diagram.

2.2. Aims

The primary aim of this study is to evaluate the effectiveness of an integrated adult- and child-focused obesity treatment approach. We hypothesize that Parent+Family-based will result in greater percent weight loss in parents and reductions in BMIz in children over 9 months compared to Newsletter +Family-based condition. We also hypothesize that Parent +Family-based will result in significantly better dietary intake (daily kilocalories, servings of fruits and vegetables, sugar sweetened beverages, beverages) and increases in moderate-to-vigorous physical activity and weight-related quality of life. Further, this study will examine multiple important mediators and moderators of treatment success, including attendance, reciprocal modeling operationalized as parent or child weight loss, family functioning, and genetic causal attributions. Lastly, this study aims to explore reach (participation rates and representativeness) from primary care versus school settings and the impact of nurse engagement on participant reach and attendance.

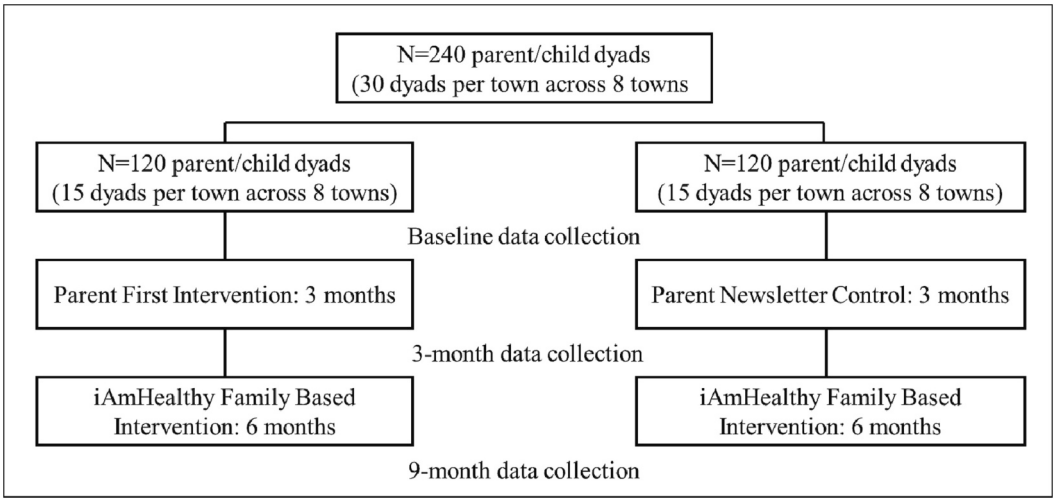

Fig. 1. Study Board (IRB).

2.3. Site and participant recruitment

2.3.1. Schools and clinic recruitment

Site recruitment will focus on onboarding eight rural schools and eight rural medical clinics. Rural is defined based on either the US Census Bureau Criteria as city and/or county population < 20,000 or the Rural Urban Commuting Area Codes of 4 or greater [29]. Study information will be disseminated to potential clinics and schools. Once a school or clinic expresses interest, the school nurse and/or clinic nurse who will champion the study will be enrolled in the Rural Nurse Engagement Collaborative (see below) and trained to partner with the staff member from a reciprocal school/clinic site in their town (i.e., clinic staff will be asked to contact and solicit participation from school staff, and vice versa). For a town to be enrolled, they must have an engaged study champion at each location and agree to recruit 30 parent/child dyads.

2.3.2. Rural nurse engagement collaborative

The primary purpose of the Rural Nurse Engagement Collaborative is to develop an implementation strategy aimed at enhancing reach and sustainability of the intervention. Development of the Collaborative is guided by the Behavior Change Wheel [30] using environmental restructuring, training, modeling, and enablement interventions to increase recruitment behaviors of school and clinic nurses. The Collaborative will capitalize on local telehealth implementation leaders at rural sites who have insider understanding of the culture and informal communication channels and are key in creating cross-sector partnerships for integrating and sustaining telehealth solutions into small communities. The Collaborative will include bi-weekly to monthly meetings led by nurses on the study team who have a history in nurse training, leadership, implementation, and engagement. Meetings will focus on the required paperwork and training related to the study, individualized plans for implementing recruitment, sharing successful recruitment methods, and nurse-selected topics for growth (e.g., cross-sector collaboration, leadership). During the later phases of the study, the Collaborative will focus on discussion of dissemination of findings to rural school and clinic stakeholders as well as possibilities for sustaining the program.

2.3.3. Parent-child recruitment

School and clinic nurses will both facilitate recruitment. Each clinic will develop a list from the electronic medical record of eligible patients. The clinic nurse will use the list as needed to proactively contact patients. School nurses will send a flyer to all children in the 1st-5th grades, asking interested parents to contact the study team. Where school-based BMI screening is done, school nurses will generate a list of all children in 1st thru 5th grades with a BMI percentile >85th and will contact these parents proactively. Recruitment will also occur by primary care providers and other school/clinic staff directly referring parents and children during routine medical visits or school meetings. Nurses will track key parameters of recruitment and report these during their weekly Collaborative meetings. Each clinic and school nurse pair will recruit approximately 30 parent/child dyads. Eligibility criteria for parents and children is summarized in Table 1.

2.4. Randomization

Each town will recruit 30 parent/child dyads, 15 of whom will be randomized to start with iAmHealthy- Parents First and 15 of whom will be randomized to start with a Newsletter Control. Randomization will occur after all 30 dyads have been recruited and will be stratified by the sex of the parent/child pair (mother/daughter versus other pairs) based on evidence that mother/daughter pairs may have worse parent and child outcomes [31].

Table 1
Inclusion and exclusion criteria.

	Inclusion Criteria	Exclusion Criteria
Child		
	BMI percentile >85th 1st-5th grade or 6–11 years old	A sibling is enrolled in the study
Parent		
	BMI 27–50 kg/m^2	In the past 6 months, myocardial infraction, stroke, or cancer diagnosis History of bariatric surgery Pregnancy in last 6 months or planned within 1 year
Parent and Child		
	Live in a rural area (city and/or county population < 20,000; RUCA = 4–10)	Significant developmental, cognitive, or medical issue (e.g., cancer, intellectual disability) known to school/clinic
	Speak English	Planning to move to a non-participating site
	Available at the times the intervention is offered	

2.4.1. Technology and scheduling

All sessions will occur over a HIPAA-compliant cloud-based platform (Zoom). Participants will use their own equipment and data plans to participate in the program. For participants for whom this is a hardship, tablets with data plans will be provided. Intervention groups will be delivered to family homes at times that are convenient for participating families. If a participating family misses a group session, they will receive a makeup session.

2.4.2. Parents first intervention

The parent intervention is group-based comprehensive lifestyle intervention modeled after the national Diabetes Prevention Program [27] and the Look AHEAD Lifestyle Intervention [28]. The focus of the parent intervention is on the parent's own behavior. The parent intervention is guided by a social-cognitive framework emphasizing factors influencing self-efficacy [32]. Sessions occur on a weekly basis for 12 weeks. Parents will continue to check in on their own goal attainment and receive accountability, feedback, and support during the following 6 months simultaneous to the family-based intervention. The primary objective is to decrease caloric intake and increase physical activity to produce gradual weight loss with an individual goal of 10% weight loss followed by maintenance of diet and physical activity behaviors. During weight loss, participants receive instructions to follow a reduced-calorie diet that includes a calorie goal and ≥ 5 one-cup fruit and vegetable servings per day. To facilitate adherence, pre-portioned meals are recommended in the early weeks of the program [33,34] during which time parents learn skills to transition to preparing family meals. Participants are provided with Garmin activity monitors and scales and commercially available apps for self-monitoring diet and physical activity (the MyNetDiary app integrates dietary tracking data and Garmin data; the Garmin Connect app includes additional information from the Garmin devices). Interventionists will have access to review logs through both apps and provide feedback within MyNetDiary.

Behavioral strategies (with emphasis on self-monitoring, goal setting, stimulus control, and problem solving) are taught and reinforced throughout the program. The intervention has been tailored to the needs of families in rural settings (summarized in Table 2). In addition, topics address needs unique for parents, including fast and family-friendly reduced calorie recipes, family-focused strategies for meal planning and cooking ahead, communicating excitement with children about the healthy changes being made, and making physical activity fun and integrating it into child activities (e.g., walking around the field during sporting events).

Table 2
Rurally tailored intervention components.

Previous Findings regarding Rural Communities	Tailored Intervention Component
Low sidewalk availability [35]	Providing alternative free home-based activities when walking is not feasible
Oriented towards work and family [36]	Linking behavior change to cultural values related to hard work and family priorities
Limited access to fast-food restaurants [37]	Decreased focus on fast food
Family and friends are key influencers on diet [38]	Increased focus on eating at social gatherings; Providing recipes of low-fat, high fruit and vegetable versions of traditional "country" or "potluck" dishes
Few outlets for community physical activity [35]	Problem solving barriers to PA facilities and providing physical activity sessions
Parental concerns over child self-esteem [39]	Increased attention to self-esteem
Limited access to low calorie and low-fat food at grocery stores [39]	Problem solving barriers to healthy food access (e.g., providing tips for which low calorie/low fat foods have a long shelf life and can be bought in bulk)
Increased poverty [40]	Providing information about how to shop on a budget
Lower educational attainment [40]	Simplified educational materials and self-monitoring forms

2.4.3. Newsletter control

Consistent with previous obesity treatment studies [41], parents in the Newsletter+Family-based group will rceive monthly newsletters for the first 3 months of the study. The newsletter control intervention reflects common practice educational/informational content such as healthy lifestyles tips and psychoeducation regarding goal setting, self-monitoring and problem solving, and a copy of the Obesity Action Coalition's Understanding Your Obesity Treatment Options Handbook. Utilizing this education control allows for the control group to continue to be involved in the study waiting for the family-based intervention.

2.4.4. iAmHealthy family-based pediatric intervention

The iAmHealthy Family-Based intervention is an intervention tailored for rural families (see Table 2) based on Cognitive Behavioral Theory [42] Child Weight Theory [43] key findings from previous qualitative research with rural parents [39]. iAmHealthy consists of both group and individual sessions (summarized in Table 3). Parents and children work together throughout each session, and both will be required to attend for the entire meeting. Additional family members are encouraged to attend. The intervention has a 12-week intensive phase of weekly group sessions followed by a 3-month period of monthly group sessions. The group sessions focus on behavioral, nutrition, and exercise topics [44] and contain both activities and didactic lessons. These topics are discussed at the individual, family, and school/community level, allowing families to discuss barriers as well as facilitators unique to their rural communities. Each week of the intervention, families will alternate between 30-min individual coaching sessions and physical activity sessions. During the individual coaching sessions, families will complete homework assignments with intervention staff and focus on goal setting, problem solving of barriers, and reinforcement for tracking. Families will also attend physical activity virtual sessions with the staff which will include interactive and energetic games and activities and be provided with activity monitors to facilitate self-monitoring. Data from the Garmin physical activity tracker will be used during the individual health coaching sessions. The total intervention (including group sessions, individual coaching sessions, and physical activity sessions) includes 27 contact hours, which exceeds the recommendation by the USPSTF to maximize clinical effectiveness (26 contact hours over a 6-month period).

2.4.5. Interventionists and fidelity

Interventionists include research staff (i.e., Registered Dietitians,

Table 3
Weekly schedule.

Week	Group Sessions	Health Coaching	Group Physical Activity
Week 1	Parents First Session 1**		
Week 2	Parents First Session 2		
Week 3	Parents First Session 3		
Week 4	Parents First Session 4		
Week 5	Parents First Session 5**		
Week 6	Parents First Session 6		
Week 7	Parents First Session 7		
Week 8	Parents First Session 8		
Week 9	Parents First Session 9**		
Week 10	Parents First Session 10		
Week 11	Parents First Session 11		
Week 12	Parents First Session 12		
Week 13	iAmHealthy Family Session 1		
Week 14	iAmHealthy Family Session 2	Health coaching 1	
Week 15	iAmHealthy Family Session 3		Group PA Session 1
Week 16	Parents First Session 13	Health coaching 2	
Week 17	iAmHealthy Family Session 4		Group PA Session 2
Week 18	iAmHealthy Family Session 5	Health coaching 3	
Week 19	iAmHealthy Family Session 6		Group PA Session 3
Week 20	Parents First Session 14	Health coaching 4	
Week 21	iAmHealthy Family Session 7		Group PA Session 4
Week 22	iAmHealthy Family Session 8	Health coaching 5	
Week 23	iAmHealthy Family Session 9		Group PA Session 5
Week 24	Parents First Session 15	Health coaching 6	
Week 25	iAmHealthy Family Session 10		Group PA Session 6
Week 26	iAmHealthy Family Session 11	Health coaching 7	
Week 27	iAmHealthy Family Session 12		Group PA Session 7
Week 28	Parents First Session 16	Health coaching 8	
Week 29			Group PA Session 8
Week 30	iAmHealthy Family Session 13	Health coaching 9	
Week 31			Group PA Session 9
Week 32	Parents First Session 17	Health coaching 10	
Week 33	iAmHealthy Family Session 14		Group PA Session 10
Week 34		Health coaching 11	
Week 35			Group PA Session 11
Week 36	Parents First Session 18	Health coaching 12	
Week 37	iAmHealthy Family Session 15		Group PA Session 12

Note. Participants in the Parent+Family-based group will receive all sessions in Table 2. Participants in the Newsletter+Family-based will receive only the shaded sessions and three newsletters on the starred weeks (**).

Exercise Specialists, masters-level Counselors, and PhD-level psychologists) who are cross-trained in both the parent only intervention and the family-based iAmHealthy intervention. The lead interventionist for the parent-only groups will serve as the co-interventionist for the family-based groups, and vice-versa. The primary investigators will provide weekly supervision, review recordings of sessions, and provide feedback. Treatment fidelity will be measured with a developed fidelity checklist. Fidelity coding will occur by research staff that are not involved in intervention delivery. The primary investigators will discuss fidelity findings and re-train staff as necessary.

2.5. Outcome measures

See Table 4 for a measurement timeline. All measures will be used in both study groups (intervention and control). All questionnaires will be administered remotely via REDCap [45,46] (Research Electronic Data Capture). REDCap is a secure, web-based software platform designed to support data capture for research studies.

2.5.1. Primary outcome measure

Weight/BMIz: All families will be provided with a Garmin Index S2 smart scale (Garmin Ltd., Olathe, KS, USA) that comes with cellular connectivity and a web-based monitoring interface making weights taken at home accessible to the research team. Standing height will be assessed in triplicate via a tape measure provided to the family. At a scheduled time, parents and children will log into a virtual session and complete height and weight measurements with monitoring and support from study personnel.

2.5.2. Secondary outcome measures

Physical Activity Monitors: Both parents and children will be provided with a Garmin Vivofit 4, (Garmin Ltd., Olathe, KS, USA) an accelerometer-based activity monitor worn on the participant's wrist allowing device-based measurement of physical activity and sleep. Garmin activity monitors have been shown to have acceptable validity for measuring activity in children and adults. An advantage of the Garmin over many research-based monitors is that it supports goal setting and monitoring through user feedback. Participants will be asked to wear the monitor throughout the intervention with an emphasis on wearing their monitor for 7 consecutive days at each of the assessment periods. Wear time will be identified via a combination of steps and motion intensity measured for each 15-min period of the day. Participants will be required to have a minimum of 4 of 7 days to be included in analyses and 10 h/day of wear time for a valid day [50,51]. Measures will include average daily step count and total active minutes.

Child Physical Activity Questionnaires: Three questionnaires will measure child physical activity. First, the Exercise Vital Sign [52] which assesses the average self-reported time spent exercising. Second, the "moderate to vigorous physical activity" screening measure [53] which assesses parent report of the number of days a child is physically active for at least 60 min. Finally, the PROMIS Parent Proxy Physical Activity Measure [54] which measures how often parents report in the past 7 days that their child engaged in various physical activity.

Adult Physical Activity Questionnaire: The Modifiable Activity Questionnaire will be used to measure adult participants' leisure-time physical activity over the past 7 days [55]. Leisure-time physical activity will be calculated as the Metabolic Equivalent of Task (MET) hours per week (MET-hr/week) and estimated by multiplying time (in hours) spent in an activity by the activities estimated MET and summing across all activities [56].

Child Diet Questionnaire: Parent-reported child dietary intake will be measured using a modified version of the Children's Eating Habits Questionnaire–food frequency section (CEHQ-FFQ). The CEHQ-FFQ was designed to estimate the eating behaviors and intakes for each of the major food groups and fast-food intake [57]. An example question parents are asked is, 'In the past month, how many times has your child eaten (e.g., dark green vegetables, fruits)?' The CEHQ-FFQ' has demonstrated preliminary predictive validity [58] and reproducibility [59].

Adult Diet Questionnaire: The Rapid Eating Assessment for Participants -Shortened (REAP-S) version [60] estimates adult diet quality by assessing weekly frequency of 13 food types (e.g., "In an average week, how often do you eat fried foods such as…"). The REAP-S has demonstrated good convergent, predictive, and discriminative validity [60,61].

Quality of Life: Parents will complete the Impact of Weight on QoL [62], a 31-item self-report measure with five subscales: physical function, self-esteem, sexual life, public distress, and work. Parents and children will also complete Sizing Them Up [63], a 22-item parent report measure of health-related quality of life for their child, and Sizing Me Up [64], a 22-item self-report of child weight-related quality of life. Each of these measures has a total score and 6 subscales (Emotional, Physical, and School Functioning, Social Avoidance, Positive Social Attributes, and Mealtime Challenges).

Attendance: The percentage of sessions a family attends.

Reciprocal influence: Parent response (% weight loss) will be evaluated as a mediator for child response to treatment, and child response (change in BMIz) will be evaluated as a mediator for parent response.

Family Functioning: Parents will complete the Family Assessment Device [65] a measure of structural, organizational, and transactional characteristics of families including a general family functioning scale.

Genetic Attributions of Familial Obesity: Parents will complete a 2-item Likert scale [66] that assesses perceived genetic role for weight status and potential for weight loss.

2.5.3. Exploratory outcome measures

Reach Measures. Reach, defined as participation rates and representativeness of enrolled participants compared to the target population [25], will be compared across school and clinic recruitment settings. Participation rates will be calculated in multiple ways to include the following: 1) the percentage of individuals on lists who respond and 2) the percentage of eligible respondents who enroll [67]. Enrolled participants will be classified as recruited from the school or clinic according to participant self-report of how they heard about the study, or if recruited from both channels, which one had the most influence on their

Table 4
Measurement timeline.

	MONTH		
	0	3	9
Weight: Adult: % weight loss; Child: BMIz; Additional timepoint captured via Smart scale at 7 months	x	x	x
Physical Activity; Vivofit 4; Adult: Modifiable Activity Questionnaire (MAQ); Child: Exercise Vital Sign (EVS), "Moderate to Vigorous Physical Activity" Screening Measure, PROMIS Parent Proxy Physical Activity Measure	x	x	x
Diet; Adult: Rapid Eating Assessment for Participants -Shortened version (REAPS); Child: Children's Eating Habits Questionnaire–food frequency section (CEHQ-FFQ)	x	x	x
Weight-Related Quality of Life; Adult: Impact of Weight on QoL (IWQOL-L); Child: Sizing Me Up (22-tiem child self-report) and Sizing Them Up (22-item parent proxy)	x	x	x
Attendance: percent of sessions		x	x
Reciprocal influence (parent response as mediator for child; child response a mediator for parent): operationalized as adult % weight loss or child change in BMIz		x	x
Demographics and medical history/update: age, race, ethnicity, income, free/ reduced lunch status, individuals living in the home, parental education/ employment, co-morbid conditions	x		x
Family Functioning; Adult: Family Assessment Device	x		x
Genetic Attributions of Familial Obesity; Adult: 2-item Likert scale assesses perceived genetic role for weight status and potential for weight loss	x		x

participation. Representativeness will be assessed by comparing demographics (age/grade, sex, race/ethnicity, BMI where available) between enrolled participants and non-participants including 1) potential participants on recruitment lists and 2) those who are screened but do not enroll. In addition, we will conduct semi-structured interviews with parent participants [39,68] to gain greater contextual understanding of factors influencing local reach and implementation. Parent participant interviews will focus on their experience being referred from schools and/or clinics, as well as facilitators and barriers to attending sessions, initiating health behavior changes, and maintaining these changes.

Nurse/staff engagement: School and clinic nurses will complete three scales from the Engage for Equity Project [69], a measure of engagement in a community-engaged research project. The scales to be completed include Commitment to Collective Empowerment, Partner and Partnership Transformation, and Projected Outcomes. In addition, we will conduct semi-structured interviews focusing on the nurses' experiences with the Collaborative, with implementing study activities, and with collaborating with their school/clinic partner. This process evaluation will provide in-depth information to understand facilitators and barriers to reach and implementation and 'how-to' information for sites who might want to establish similar collaboratives in the future.

2.6. Analysis

2.6.1. Power analysis

A 2-level model is the primary analysis proposed to address study aims and power is estimated for that. We have 0.80 power to detect differences in intercept equivalent to $d = 0.39$ given an ICC of 0.05 with the proposed sample size, with cluster sizes of 15 per group with 0.80 power. Even if recruitment is more challenging than planned, with clusters as small as 12, our power would not change meaningfully. Thus, the 16 clusters (8 sites with 2 clusters per site) with 15 participants per cluster, even allowing for attrition, will be adequate to address the primary aims of this study.

2.6.2. Missing data

Full information maximum likelihood estimation will be used for the multilevel models. For variables brought into the likelihood function, any missing cases are assumed missing at random, which means random only after conditioning on model predictors and the observed outcomes. Reasons for family departure can be tracked and included as model predictors to help reduce the bias that might otherwise be created. Attrition will be examined across conditions to ensure that it remains low and unrelated to condition, as is anticipated.

2.6.3. Quantitative analysis plan

Multilevel modeling (MLM) analyses will be conducted using SAS PROC MIXED or GLIMMIX to accommodate the clustering inherent in the data. Participants (level-1 units) are nested in community-based clusters (level-2 units). This will account for the dependency between participants, as multiple families will be nested within treatment groups in each community [70]. Due to the small number of clusters in our sample, we will follow the techniques recommended by McNeish (2017) for MLM [71]. Fixed effects for community, and for treatment type will be included at the cluster levels. This approach will result in models with appropriate standard errors for the clustered sample. Baseline equivalence will be examined, and parent and child characteristics which differ across conditions as indicated by standardized differences will be evaluated for inclusion in adjusted models. Sensitivity will be examined by running these models both with and without the identified covariates. Treatment response will be tested by examining differences in intercepts by condition. Effect sizes for each outcome will be calculated using the difference in the model estimated means for each group over the pooled observed standard deviation at baseline.

Unconditional models will be examined for each dependent variable to determine the amount of between and within cluster variances. Each of the outcome variables will be analyzed separately. To analyze our first hypotheses, we will test for differences in percent weight loss from baseline/BMIz level at the 9-month time point; the model for BMIz will control for baseline levels. For the diet outcomes which assess similar constructs, we will use a modified Bonferroni adjustment to control for family-wise error rate. Because some of the diet variables are counts of servings, the distributions will not be appropriate for use in the traditional multi-level models, and appropriate transformations or link functions will be applied in the analyses, such as the negative binomial distribution will be used, requiring a switch to Generalized Linear Mixed Models. To analyze potential mediators and moderators including attendance, family functioning, or genetic causal attributions, each mediator or moderator will be added individually at the person or cluster level and analyzed separately by outcome. Because both parent and child participate, the dyad partner variables will also be included as appropriate. Physical Activity models will look similar to the weight and diet models. Because of the limited number of outcomes and the anticipated normal distributions, we do not plan to use a modified Bonferroni correction or anticipate transforming the outcome variable or using link functions in modeling. Additionally, measures of reach and the association of nurse engagement/leadership measures to participation rates, attendance, and retention will be exploratory and descriptive.

2.6.4. Qualitative analysis plan

Inductive thematic analysis [72] will be used to analyze interviews. Results of the nurse/staff engagement measures will be compared to themes that emerge from nurse/staff interviews using a convergent parallel mixed methods approach [73] to achieve a holistic interpretation of the findings. Peer debriefing will be used to challenge interpretations of the data and resolve discrepancies prior to dissemination, and joint displays will be utilized to display the integrated qualitative and quantitative analyses in a way that provides new mixed methods insights [74]. Dedoose [75] will be used to assist the researchers in efficient and organized data storage, coding, retrieval, comparing, and linking.

3. Conclusions

This study is the first to join a highly effective adult obesity treatment program with a pediatric family-based program to assess the impact of helping parents with their own health behaviors first. Further, this study is the first to include a comparison of clinic- and school-based recruitment settings in terms of participation rates, attendance, or retention. If support for iAmHealthy Parents First is obtained, there is the potential for this project to exert a sustained, powerful influence on the field of family-based obesity treatment and research recruitment in rural areas.

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Declaration of Competing Interest

None of the authors have any competing interests or financial interests to disclose.

Data availability

No data was used for the research described in the article.

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