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A comparative effectiveness trial of two family-based childhood obesity treatment programs in a medically underserved region: Rationale, design & methods

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ABSTRACT

While there is a large body of literature documenting the efficacy of family-based childhood obesity (FBCO) treatment interventions, there is little evidence that these interventions have been systematically translated into regular practice — particularly in health disparate regions. To address this research-practice gap, this project was guided by a community advisory board (CAB) and the RE-AIM planning and evaluation framework within a systems-based and community-based participatory research approach. Families with overweight or obese children between 5 and 12 years old, in the medically-underserved Dan River Region, were randomly assigned to one of two FBCO treatment programs (*i*Choose vs. *Family Connections*) delivered by local Parks & Recreation staff. Both programs have previously demonstrated clinically meaningful child BMI z-score reductions, but vary in intensity, structure, and implementation demands. Two clinical CAB partners embedded recruitment methods into their regional healthcare organization, using procedures representative to what could be used if either program was taken to scale. The primary effectiveness outcome is child BMI z-scores at 6-months, with additional assessments at 3-months and at 12-months. Secondary goals are to determine: (1) reach into the intended audience; (2) effectiveness on secondary child and parent outcomes; (3) intervention adoption by organizations and staff; (4) fidelity, cost, and capacity for intervention implementation; and (5) maintenance of individual-level changes and organizational-level sustainability. This research addresses literature gaps related to the features within clinical and community settings that could improve both child weight status and the translation of FBCO interventions into typical practice in medically-underserved communities.
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1. Introduction

Obesity prevalence is a public health concern that is a national priority [1–3]. The outcomes of sustained obesity include diabetes, cardiovascular disease, and some forms of cancer [4]. Increased rates of obesity in children are related to 'adult' diseases such as type 2 diabetes and hypertension presenting during childhood [5]. Due to the alarming prevalence and impacts of childhood obesity [1–3], there is a large body of literature and numerous systematic reviews documenting the efficacy of family-based childhood obesity (FBCO) interventions [6–19]. Yet each of these programs vary in appeal from both an organizational perspective (e.g., costs and resources to deliver the intervention, expertise of those who will deliver the intervention) and family perspective (e.g. number of intervention sessions, number of contact

Abbreviations: FBCO, family-based childhood obesity; CER, comparative effectiveness research; RCT, randomized controlled trial; CBPR, community-based participatory research; DRR, Dan River Region; RE-AIM, reach, effectiveness, adoption, implementation, maintenance; IVR, interactive voice response; CAB, community advisory board; PAT, parent advisory team

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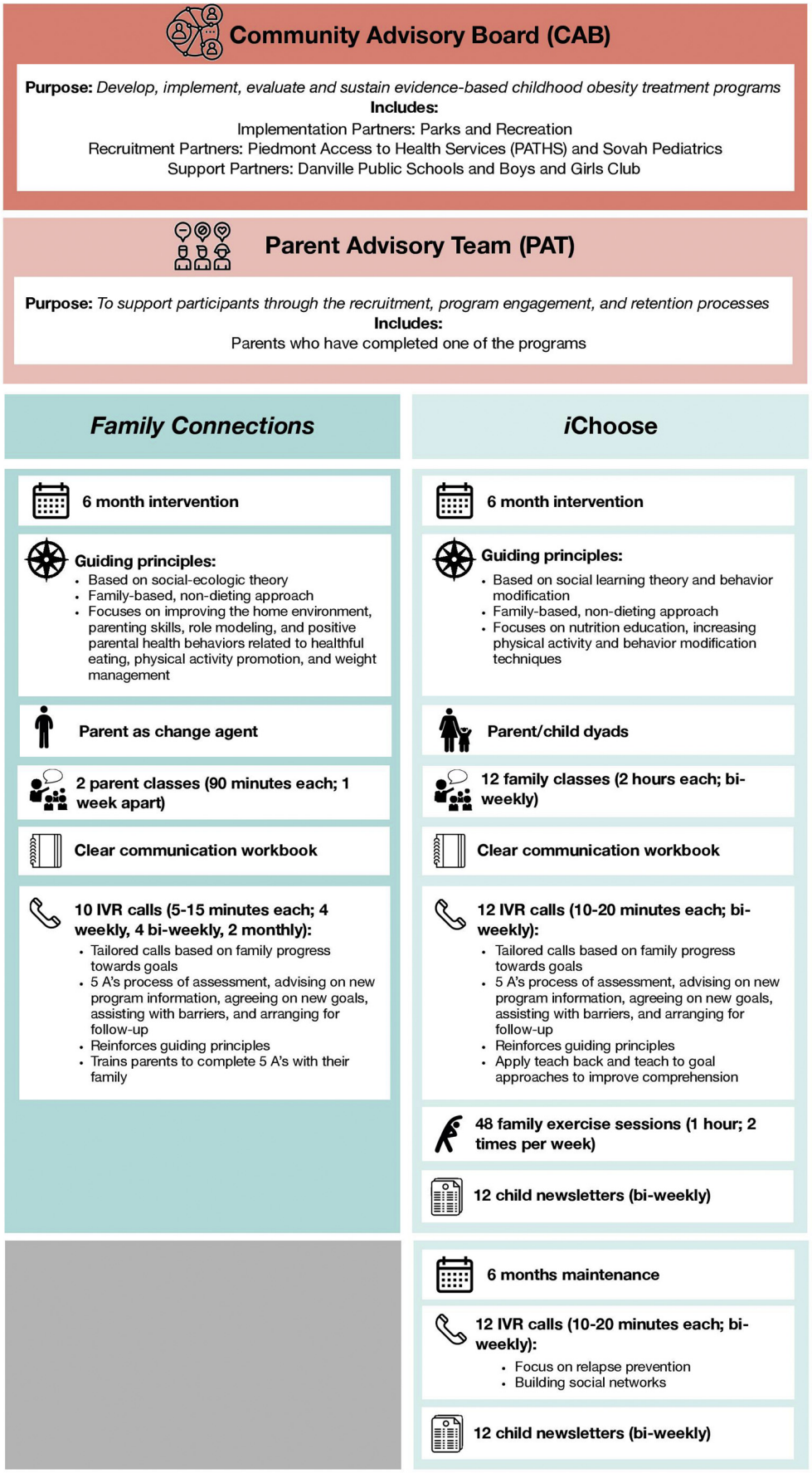

Fig. 1. Overview of family-based childhood obesity interventions: ichoose vs. *Family Connection*.

hours, duration of the program). As such, FBCO intervention planning, implementation and evaluation should apply a systematic approach that considers both organizational and family/individual level factors as well as assesses the internal and external validity of intervention findings [20–22].

When further examining FBCO interventions, those that include 26–75 contact hours or more are typically the most successful in reducing weight status [23,24]. However, programs that include a high number of contact hours over 6 months are also associated with low adherence [25]. In healthcare-based pediatric weight management programs delivered at scale, it is typical to see high attrition (> 60%) during a 6-month (or shorter) program [25–31]. This lack of adherence is problematic given consistent finding that higher treatment adherence is associated with a higher likelihood of success [32,33]. Compounding adherence issues, is a trend for child weight status reductions to move towards baseline values, with a few exceptions [11,14], once a FBCO intervention is completed [34–38]. As a result, several research teams have developed and tested FBCO maintenance interventions. Findings have been mixed, with successful maintenance in some [39–42], but not all FBCO interventions [43–45].

Despite the promise and large body of evidence, there is little evidence that any FBCO treatment intervention has been systematically translated into regular practice or reaches a large number of families in health disparate regions [34]. Of particular concern is the persistence of obesity-related disparities for children from low income, minority children in geographically dispersed and medically underserved regions [46,47]. Also, there are substantial literature gaps related to the features within clinical and community settings, and intervention design and structure, that could improve the translation of FBCO interventions into typical practice settings. There is a clear need to test lower-contact hour interventions in typical community settings where high-need audiences lack access to effective programming and local providers have limited resources for delivery [34].

By applying systems-based and community-based participatory research (CBPR) approaches, this study was designed to collectively address these gaps in the literature [48–52]. Importantly, this research builds from a prior FBCO pilot trial [53,54] and an established childhood obesity partnership that includes clinical, community and research partners in the health disparate Dan River Region (DRR) [55,56]. This current comparative effectiveness research (CER) study and randomized controlled trial (RCT) evaluates two FBCO treatment programs (*i*Choose vs. *Family Connections*). Though both of these FBCO program have previously demonstrated clinically meaningful effects for improving BMI z-scores in children, they vary in intensity, structure and implementation demands [11,15–18,32]. The long-term goal of this research is to help reduce childhood obesity disparities in the medically underserved DRR by identifying an effective FBCO that can be sustained using local community and clinical resources.

2. Material and methods

2.1. Study overview and evaluation framework

This research aligns with systems-based and CBPR strategies and is also guided by the RE-AIM (reach, effectiveness, adoption, implementation, maintenance) planning and evaluation framework. Systems-based approaches integrate research, practice, and patient perspectives to improve the movement of the evidence-base from the scientific domain and into the community domain [48,49]. This approach highlights the importance of priorities, cultural norms, and context; tacit practice-based knowledge; relationships within and across community and clinical organizations; and the strategic processes that influence decision-making. CBPR is an action-oriented research approach that aims to build community capacity, promote equitable community-academic partnerships, encourage community participation in all aspects of the research process, and stimulate program sustainability [50–52]. The RE-AIM framework has an explicit focus on addressing organizational and individual outcomes while emphasizing both internal and external validity—to allow for a heightened likelihood of implementation in typical community settings [21,22]. Importantly, the RE-AIM framework aligns with CBPR and systems-based approaches and allows for vertical (e.g., implementation decisions for community stakeholders) and horizontal (e.g., adoption across different sectors) assessment [49].

Focused on effectiveness, the primary aim of this study is to determine the relative changes in child BMI z-scores of *i*Choose versus *Family Connections* (see Fig. 1). *i*Choose is adapted from an established evidence-based FBCO, Bright Bodies [16–18,53,57]. The first 6-months of the program includes 12 bi-weekly family classes, 48 family exercise sessions, 12 interactive voice response (IVR) support calls to parents or caregivers (hereafter referred to as parents), and bi-weekly child newsletters. An additional 6-month maintenance phase includes bi-weekly IVR calls to parents and newsletters to children. *Family Connections* [32] is an adaptation of Golan's Home Environmental Change model [15] that focuses exclusively on parents as the agents of change. *Family Connections* has fewer sessions (2 parent classes) and fewer IVR support calls (10 calls) over a shorter period of time (6 months). The program delivers the intervention to parents only, and promotes physical activity, but does not include structured exercise sessions. Adapted from evidence on the utility of community health workers [58–60], a parent health advisor component is used in both FBCO interventions to support the recruitment, engagement and retention of families [61].

2.1.1. Study aims and hypotheses

The primary and secondary goals are consistent with the RE-AIM framework, including addressing the: **r**each of the intervention into the target population and the representativeness of those who participate; **e**ffectiveness of the intervention in reducing child BMI z-scores (primary outcome) and improving quality of life as well as changing behavioral and parent outcomes; **a**doption of an intervention by organizations and staff within those organizations; fidelity, cost of, and capacity for **i**mplementation of the intervention across settings and staff; and **m**aintenance of individual level changes beyond intervention completion and intervention sustainability once research support has ceased. For the primary outcome, it is hypothesized that children in both conditions will significantly reduce BMI-z scores when compared to baseline, but *i*Choose participant reductions will be significantly larger than *Family Connections* participant reductions.

2.1.2. Study region and population

The DRR is located in south central Virginia and north central North Carolina and includes the city of Danville and Pittsylvania, Henry and Caswell Counties. The DRR is a confluence of social determinants of health that includes low socio-economic status, a high proportion of racial minorities, and small regional cities that lack resources to address obesity [62–65]. This a federally designated, medically underserved area burdened with educational, economic, and health disparities. Regional unemployment rates (ranging from 4% to 6%) are somewhat higher than the current state (3.1%) and national (3.9%) averages, 34% of residents are black, 15.3% live below the Federal Poverty Level, and only 18.6% have obtained a bachelor's degree [64]. Although childhood obesity data are limited, one local school district showed 17% of 1st graders were overweight and 19% were obese [66]. By 5th grade, this cohort increased prevalence to 19% overweight and 36% obese. This rate of obesity is 3 times higher than state averages (~11% of VA youth are obese). Prevalence of adult obesity (~33–35%) is also higher than state averages (29%) [65].

2.2. Preliminary work

2.2.1. History of regional childhood obesity treatment intervention research efforts and partnership development

The regional childhood obesity Community Advisory Board (CAB) and CBPR partnership leading this research was originally initiated in January 2013 after being awarded a National Institutes of Health R24 three-year planning grant. The aims of this planning grant were to advance community capacity to develop and implement a FBCO initiative in the DRR and to pilot test a FBCO intervention. The planning grant end goal was a FBCO ready for large scale testing within existing systems in the DRR. Local organizations with missions related to child health and services that target low socioeconomic families were involved and represented a balance of clinic-based and community-based health systems: Pittsylvania/Danville Health District, Children's Healthcare Center (now Sovah Pediatrics), Danville Parks & Recreation (i.e., Parks & Rec), and Boys & Girls Club of the Danville Area. The CAB also included an interdisciplinary team of academic investigators.

During this planning grant, CAB partners were involved in all phases of the research [55,56]. In the initial phase, the CAB selected and adapted a FBCO intervention for the DRR. As the study progressed, the partners were also involved in referrals and recruitment, data assessments, implementing the interventions, and efforts aimed at promoting family engagement and retention [53]. Details of CAB members' perceptions on how participatory processes influenced the collaborative partnership, research and sustainability of efforts were capture through mixed-methods process evaluation and is detailed elsewhere [55,56].

Selecting an FBCO program that was the best fit with community resources occurred within the first several months and across three day-long meetings. CAB members reviewed the available RE-AIM information available on FBCO programs and presented local resources that could be applied to reducing childhood obesity in the region. CAB members then rated and rank ordered three top FBCO candidate programs based on alignment with available community resources [53]. Discussion of rankings determined that Bright Bodies was the best fit for the DRR, followed by *Family Connections*, and then the Traffic Light program [53]. After this determination, the CAB members identified a number of necessary adaptations to Bright Bodies, including a need to reduce the reading difficulty of the program manual, adapt graphics and nutrition information for cultural appropriateness, reduce the frequency and duration of program activities, and shorten the program to improve reach and retention. To address these issues and avoid infringing on the on the copyright of Bright Bodies program materials, a CAB subcommittee made up of research and community members used a Diffusion of Innovation approach towards intervention re-invention based on the underlying evidence-based principles reported on Bright Bodies in the literature [16–18,67]. Specifically, the subcommittee completed a content analysis of each article to develop a set of skill-based learning objectives that reflected the core components and principles of the Bright Bodies intervention [68]. Finally, the subcommittee used the learning objectives to name the intervention (*i*Choose) and develop materials for a 3-month program, including parent and child workbooks, biweekly family session lesson plans and activities, fidelity checklists, and presentation materials, scripts for guidance on biweekly telephone support calls to parents, biweekly newsletters for children, and lesson plans and fidelity checklists for three supervised exercise sessions per week [57].

2.2.2. Childhood obesity treatment intervention feasibility evaluation

Subsequently, three stages of iterative intervention testing/formative feedback loops were implemented to determine the reach, effectiveness, and feasibility of the *i*Choose program [53]. Findings revealed that *i*Choose had an 18% reach using a referral strategy implemented by CAB partners from Children's Healthcare Center and the health department. The strategy included identifying potentially eligible families using the system medical record, sending a letter on behalf of each family's pediatrician, and completing telephone follow-up to screen and recruit eligible families. Resultant participants were representative of the target population on age, gender, ethnicity, and race. Effectiveness was demonstrated by modest, but significant initial reductions in child BMI z-scores at three months (post program mean change = − 0.05; $p < .05$) that were not maintained three months after the program was completed. Also, *i*Choose demonstrated similar reach, program engagement, and 3-month effectiveness among children with parents who had low and high health literate parents [54]. Finally, implementation fidelity was high and did not differ between community or research delivery agents [53]. It was concluded that *i*Choose was successful in initiating changes in BMI z-scores and could be implemented in a low resource community with fidelity, but may need to be expanded in duration with added content focused on relapse prevention to address the lack of maintenance of child BMI z-score reduction. Also, the support calls were deemed too burdensome for clinic staff and overall family engagement in *i*Choose program components were lower than desired [53].

2.2.3. Partnership advancement and subsequent participatory prioritization and planning

After the final cohort completed *i*Choose, program family graduates were invited to participate in a Parent Advisory Team (PAT) to facilitate expanding the duration of the program and to identify locally relevant relapse prevention strategies [61]. The PAT was formalized in June 2015 and began meeting on a monthly basis. At the initial meetings, PAT members were updated on the *i*Choose program results and discussed the meaning and potential sustainability of *i*Choose. Conversations then transitioned to brainstorming on the role of PAT. An immediate role that emerged for the PAT was to engage in developing a maintenance phase for *i*Choose. For much of the next year, the PAT spent most of their monthly meetings developing and pilot testing maintenance phase lessons based on principles highlighted in recent literature on maintaining reduced child BMI z-scores [39]. PAT members also envisioned further effort related to recruitment, attendance and retention [61].

The planning grant process provided critical data and insights into the development of this current CER project [53–57,61]. With a goal to improve the magnitude of weight reductions and increase the likelihood of sustaining a FBCO in the community, several key priorities emerged: (1) extend *i*Choose to a 6-month program, followed by 12 biweekly maintenance telephone calls, congruent with the 12-month Bright Bodies program duration, (2) formalize a PAT model of previous *i*Choose families to serve as a 'peer support safety net' for new program participants, and (3) deliver support calls using interactive voice response (IVR) automation to reduce the burden on community stakeholder implementation. Also, when reflecting on and interpreting the outcomes of the planning grant, the CAB and PAT identified the need to use a study design that allowed all future participants the opportunity to benefit and, with this in mind, to test alternative FBCO program options that improve reach within the broad DRR population. Thus, the CAB returned to the *Family Connections* intervention that they considered earlier in the planning grant process and rated highly for scalability [15,32].

2.3. Childhood obesity treatment study design and procedures

A systems-based approach was used as the basis for the study design and procedures [49]. Horizontal systems that included community organizations which provide services to, and interact with, the intended audience were engaged in a CAB to provide oversight and guidance on all aspects of the trial. Within each organization, vertical system representation was included in the form of personnel with program decision making authority as well as personnel who would ultimately implement key intervention activities to facilitate program recruitment, implementation, retention, and maintenance (see Table 1). While

Table 1
Roles of partners engaged in this family-based childhood obesity comparative effectiveness study.

	Recruitment	Program implementation	Program engagement & retention	Data collection
Parks & Rec	Follow-up calls for families identified through medical record reviews. Open source recruitment participation.	Deliver all parent and child nutrition, physical activity, and behavioral sessions.	Implement social support strategies to maintain engagement and increase retention. Send missed class texts with link to video mini-session.	Co-lead all data assessment time points.
Sovah Pediatrics	Identification of potentially eligible families through medical record review. Send signed letters of referral to the study from pediatricians. Initial telephone follow-up attempt.	N/A	Send physician signed letters to encourage program participation and attendance at data collection follow-up time points.	Collect reach data during recruitment calls.
PATHS	Identification of potentially eligible families through medical record review. Prepare signed letters of referral to the study from pediatricians. Initial telephone follow-up attempt.	N/A	Send physician signed letters to encourage program participation and attendance at data collection follow-up time points.	Collect reach data during recruitment calls.
PAT members	Open source recruitment participation. Attend local community events and meetings to distribute program materials and promote enrollment of families.	Attend family nutrition and behavioral sessions and engage with families during activities and discussions. Introduced in the first family sessions and assigned a group of families to support.	Send supportive text messages on approximately a weekly basis. Respond to family needs related to the program. Promote upcoming program activities.	Serve as greeters during data assessments.
Researchers	Prepare physician referral letters and send to clinic partners for signatures. Back up support for follow-up calls on physician referral letters. Open source recruitment participation.	Lead training sessions for Parks & Rec staff. Review program responsibilities with PAT.	Oversee automated text reminders (3/week) for all program sessions. Monitor IVR system for parents that request a call from Parks & Rec program leads.	Oversee all data assessment time points. Collect reach data during recruitment calls. Monitor implementation fidelity.

guided by the RE-AIM framework to ensure focus across individual and organizational outcomes, the three-year CER study and RCT developed through our systems-based approach focuses on the effectiveness and maintenance outcomes of *i*Choose when compared to *Family Connections*. Three cohorts of families (parent and child) are enrolled (i.e., Fall 2017, Spring 2018, Spring 2019) using randomization, at the child level, within each cohort. Also, a mixed-methods process evaluation is applied to evaluate program reach, implementation and capacity related outcomes.

The University of Virginia's Institutional Review Board approved this research. This study involves four distinct groups of participants including CAB members that also include program implementation partners, PAT members, children, and their parents. Adult participants (i.e., CAB members, PAT members, and parents) provide written informed consent and children provide assent. Furthermore, all clinical, community, and research partners engaged in the research processes complete IRB training before interacting with prospective or current families participating in the research.

2.3.1. Community Advisory Board (CAB): membership, structure and payments

Members of the CAB include local organizations with missions related to child health and services including health care, recreation, schools, and community systems. Specifically, CAB members include partners from Sovah Pediatrics, Piedmont Access to Health Services, Inc. (PATHS), City of Danville Parks & Rec, Danville Public Schools, and Boys & Girls Club of the Danville Area. The CAB meeting frequency varies somewhat to meet the demands of the project, but averages about three times per year. Meetings last about 4 h and are facilitated by an external facilitator. The main meeting goals are to strengthen relationships and communication among partners, review project milestones, discuss RE-AIM process data from past and on-going cohorts (e.g. reach—recruitment, retention, engagement; effectiveness—summative program evaluations from enrolled families; implementation—fidelity and instructor feedback to improve session quality), and plan logistics for subsequent phases of the research including program maintenance beyond research funding support. Attendance at the meetings averages about eight community partners and five academic partners. Three of these organizations are also subcontracted for their roles in this research (see Table 1). In contrast to other FBCO that are typically delivered by medical professionals with advanced degrees or credentials, the programs are delivered by trained Parks & Rec staff. The university research partners provide training, technical assistance, and oversight for all study related activities.

2.3.2. Parent Advisory Team (PAT): membership, structure and payments

Members of the PAT include *i*Choose program family graduates from the previous planning grant process. Initially, the PAT consisted of six parents, though this dropped to five in Cohort 2, and increased to eight in Cohort 3 when additional program graduates from this CER study were invited to participate. The PAT meet monthly in the evening for about 90 min and the meetings are facilitated by a research associate residing in the DRR. The main meeting goals are to strengthen communication among PAT and with researchers, review project milestones, review current and upcoming project related tasks, discuss challenges and success with family recruitment and engagement tasks, review process data, and plan logistics for subsequent phases of the research.

Roles of the PAT are to optimize program reach including indicators of successful recruitment, ongoing engagement, and study retention as well as facilitate implementation in both *i*Choose vs. *Family Connections* (see Table 1). The primary responsibility of PAT members includes providing a social network for families new to the program. PAT members also review program materials to ensure that they could respond to content related questions from families in the program they were supporting. PAT members are paid as study contractors, with a

payment of $200/month during active study periods (e.g. recruitment and program implementation phases) and $100/month during less active study period cycles.

2.3.3. Parent & child: eligibility criteria, recruitment and incentives

The study was designed with minimal exclusion criteria to heighten the likelihood of engaging a sample that is representative of the broader community population. To be eligible to participate families must live in the DRR, be English speaking, have a child with a BMI percentile ranking > 85%, and at least one parent (or caregiver) willing to participate in the program. For Cohorts 1 and 2, the eligibility criteria for age was 8 to 12 year-old children. This age criterion was extended to 5 to 12 year-old children for the final Cohort 3 to meet recruitment needs for the trial. Families are excluded if a child had a major cognitive impairment or if the parent or child has a contraindication for exercise.

Two main recruitment strategies are used. First, staff from two clinical systems, Sovah Pediatrics and PATHS, identify potentially eligible children through a medical chart review. Personalized letters from the child's pediatrician are then mailed to all potential families. Then clinic staff, research staff from Parks & Rec, and university research staff collaborate to execute follow-up telephone screening and recruitment calls. Up to six attempts are made to contact families, using a combination of calls and text messages. Eligible and interested families are scheduled for a baseline assessment.

Second, an open referral system that uses a variety of different strategies is being implemented. These strategies include advertisements posted in local newspapers and on Facebook. Informational flyers are also sent home through local county and city schools. Lastly, PAT members and local programming staff attend local health fairs and community events and meetings to help promote the research and recruit families. Families that respond to these open referral efforts follow a similar protocol, with initial screening occurring either via telephone or in person and with a follow-up baseline health screening for those interested and eligible.

The parent informed consent and child assent processes occur at the baseline health screening appointment, and prior to any data collection. To compensate time involved in data collection efforts, both the parent and child receive gift cards including $25 at baseline, $25 at 3-month, $50 at 6-month, and $50 at12-month assessments.

2.4. Childhood obesity treatment interventions overview, iChoose vs. Family Connection

2.4.1. iChoose

The core principles of the Bright Bodies intervention were derived from the extant literature on the intervention and used to create intervention materials for *i*Choose that are tailored to the context of a micropolitan and rural area [16–18,68]. The updated *i*Choose intervention contains: (1) Clear communication *i*Choose workbooks for parents and children that provide the basis for all *i*Choose activities to assist families in changing physical activity, eating behaviors, and child weight status; (2) 12 family classes that reduce reading demands and incorporate numerous non-print education strategies, hands-on demonstrations, and pictorial instructions (each 2-hour class is split evenly between nutrition, exercise, and behavior change topics); (3) 12 IVR calls that provide reinforcement of class objectives, personalization of goals, and apply teach-back and teach-to-goal methods (two versions of each call are used—one call for families that attend the class and one for those that did not); (4) 48 family exercise sessions to promote practice and mastery and encourage social support (12 PA sessions are integrated within the family class for a total of two sessions/week); and (5) bi-weekly child newsletters to reinforce class messages and provide fun family activities. To increase the duration and contact after the initial 24 weeks, a 6-month maintenance program is introduced that includes bi-weekly IVR calls to parents and newsletters to children. The IVR structure focuses on (1) relapse prevention through the reinforcement of program content and skill building opportunities, (2) developing and engaging with social networks of peers and in communities, and (3) goal setting and feedback relative to nutrition and physical activity outcomes.

2.4.2. Family connections

Similar to efficacy trials using Golan's model [11,15,69,70], *Family Connections* focuses only on parents as an agent of change. This intervention includes two parent classes, followed by 10 interactive voice response (IVR) automated telephone support calls over 6 months. The program materials are provided in a parent workbook using clear communication strategies and associated call journal. These materials include activities for parents to complete at home and allow for regular goal setting over the 6-month intervention and planning for relapse prevention once the program is completed. The small group support sessions are spaced one week apart followed by 10 IVR calls beginning weekly (4 weeks), biweekly (8 weeks), and monthly (3 months).

2.5. Organizational-level training and implementation

This trial uses Edmunds and colleagues' Consultee Centered Facilitation Approach as an ongoing training implementation strategy to improve and sustain program implementation fidelity and allow for continuous quality improvement on existing program activities and delivery strategies [71]. This approach includes (1) instruction and role playing on program content and underlying principles, (2) case reviews of previous implementation with program participants, (3) instructor self-reflection, evaluation, and goal setting related to implementation using fidelity data, and (4) feedback on delivery of family sessions [71]. All training activities are facilitated by a doctoral level behavioral scientist with expertise in childhood obesity treatment programs, intervention adaptation based on underlying core principles, and consultee centered facilitation. Parks & Rec and research staff supporting program implementation participate in the trainings.

The dose and temporality of the initial trainings (Cohort 1) is initiated with a 2-day onsite training (~12 h) that covers the underlying core principles of each program and reviews the initial two family/parent sessions for both *i*Choose and *Family Connections*. Biweekly trainings are then conducted for the remaining 10 family sessions for *i*Choose each lasting approximately 60–90 min using Zoom video conferencing. To facilitate each session, implementation staff review lesson plans, fidelity checklists, and a brief training video. Training videos cover key learning objectives, content, and activities for each parent session (*Family Connections*) and nutrition, parent behavioral, and child behavioral sessions (*i*Choose). Each of these videos are brief and with a target duration of approximately 15–20 min. This general pattern is followed for Cohorts 2 and 3, though without the 2-day training. As a result, training for these cohorts includes 12 video conference sessions lasting approximately 60–90 min each. The content flow of these sessions follows the 4 steps described by Edmunds and colleagues (see description above).

The targeted implementation outcome is consistently focused on implementation fidelity, but adapted during Cohort 2 to also focus on strategies to improve program retention. Approximately 4 h of training are added prior to the implementation of Cohort 2 that includes a review of research findings on strategies that could improve retention of families, identification of social support principles that could be used in family sessions to enhance retention, and collaborative development of strategies based on those principles to be added to the program lesson plans and fidelity checklists. Cohort 3 trainings maintain a balanced focus on content and retention activity implementation.

2.5.1. Organizational-level maintenance: sustainability action planning

The Sustainability Action Plan process will involve a 3-step iterative process integrated into regular CAB and PAT meetings, will begin following the final study cohort, and will focus on one, or both, of the

programs based on the extant RE-AIM data collected across the study. The first step will include gathering information through a sustainability needs assessment that considers design and implementation, organizational context, and community environmental factors that facilitate sustainability. The second step will include a re-examination of existing resources available to deliver the program(s) and potential adaptations to increase the likelihood of sustainability while ensuring that core components of the program(s) are addressed. The third step will develop action plans that pursue strategies that have been beneficial in other domains [72]. These include options to 1) produce materials to promote the program(s), 2) create a resource development committee, 3) foster and engage program champions from the PAT, 4) institutionalize strategies to keep the community involved and facilitate broad-based local ownership, 5) plan for a sustainable program delivery team, and 6) identify methods to integrate the program(s) into existing job descriptions and training procedures for the community partners engaged in strategies to reach the intended audience and implement the program components. Data from the sustainability action planning, CAB and PAT meeting minutes, the needs assessment, and specific action plans will be used to determine the likelihood of sustainability.

2.6. Data collection and measures

A manual of procedures was developed to detail standardized guidelines for assessing RE-AIM outcomes using screening telephone calls, in-person screenings and assessments, and qualitative interviews. This manual is used to train all individuals involved in calls, screening, and data collection.

2.6.1. Individual-level, child and parent measures

At the initial telephone screening, demographic information of the child and parent is collected [73–75]. To allow for reach and representativeness analysis, the collection of demographic information is also attempted among those who are eligible but decline to participate [20].

Data collection to assess effectiveness of the programs is a shared responsibility among trained Parks & Rec staff and the research team members. The assessments are held at conveniently located Parks & Rec facilities. Screenings at baseline, 6-months, and 12-months each take approximately 90 min. The 3-month screening only includes height, weight and a brief interview and takes about 10 min. Table 2 illustrates the domains assessed and measures used. Height, weight, blood pressure and waist circumference are measured by staff using research grade equipment and published guidelines [76,77]. Height and weight data are calculated into BMI z-scores for children and BMI scores for parents. Also, previously validated instruments are used to assess all secondary self-reported outcomes among children and parents, including quality of life [78,79], physical activity [80], nutrition [81–84], home environment [85], and health literacy [86–88]. The self-reported measures are administered via an automated computer-assisted program developed for this project. For children, self-reported measures were only collected among those 8 years of age and older; except for the quality of life measure which was interview administered to children < 8 years of age. At each assessment time point, BMI, blood pressure, and waist circumference numbers are reported back to parents and children in the form of a personalized 'Know Your Numbers Card,' that also identifies healthy/unhealthy ranges.

Mixed-methods program evaluation and behavior change questionnaires are also administered. At 3-months, a motivational interviewing approach is applied to assess parents' satisfaction with program randomization and level of engagement in the program components. Structured prompts are used to reinforce motivation and encourage program engagement. At 6- and 12-months a mixed-methods survey is administered to both parents and children. The quantitative section includes satisfaction ratings with program specific components [e.g. family classes, IVR calls, workbooks, exercise classes (*i*Choose only)]. The qualitative section asks about types of behavior changes made and probes on successes, challenges, and potential new obstacles. At 12-months, the qualitative section only is re-administered to parents and children.

2.6.2. Organizational-level implementation measures

Organizational level measures focus on two specific RE-AIM domains—implementation and community capacity for program maintenance. Implementation will be assessed by the degree to which the timing, content, and completion of each intervention step in the protocol is completed as intended and the cost of implementation to use for sustainability planning. Our implementation evaluation will follow recommendations of Linnan and colleagues [89], such as an examination of intervention dose delivered and received by study participants with multiple data sources including fidelity checklists, attendance records, IVR completion logs, and a qualitative exit interview with parents to assess patient-centered satisfaction with program components. For both programs, implementation costs will be captured for staff time (e.g. training, preparation, program implementation, retention strategy implementation), facility fees for intervention sessions, IVR maintenance cost, program supplies, and family materials cost (e.g. workbooks). Finally, we will assess costs related to recruitment methods through the local clinical partners to provide practical information on the resources needed to enroll a critical mass of families in a relatively short period of time.

In regards to assessing capacity, two primary activities will be used. First, both the CAB and PAT members participate in annual mixed-methods capacity evaluations. Second, CAB and PAT members will participate in a sustainability action planning process that will produce information on systems-based barriers, facilitators, and actions towards longer-term program sustainability. The instruments for the mixed-methods capacity assessment are guided by previously published measures and from previous research with these groups through the planning grant [55,56,61,90]. The quantitative survey instrument is self-completed and takes approximately 20–30 min. The semi-structured qualitative interviews are conducted by an external consultant via phone, is audio recorded, and takes approximately 45–60 min. The CAB instruments assesses 14 domains, including: communication, trust, participation and influence, leadership, group roles, problem assessment and problem solving, conflict resolution, decision-making procedures, community power, collective efficacy, accomplishments and impact, resources, sustainability, and satisfaction. The PAT instrument measures eight domains, including: communication, problem assessment, collective efficacy, leadership, participation and influence, community power, overall satisfaction, and your influence in your life and community. In addition, meeting agendas, minutes, and artifacts are tracked at each of the CAB and PAT meetings and will be used to inform capacity findings.

2.7. Power calculation and sample size

A standardized effect size of 0.73 favoring *i*Choose was calculated based on the relative 6-month differences in BMI z-scores and standard deviations for *Family Connections* (−0.07, SD = 0.112) and *Bright Bodies* as a target for the *i*Choose condition (BMI z-score reduction (−0.16, SD = 0.184). The community participatory nature of the project requires two interim analyses (one following each cohort) conducted in order to disseminate project findings to the CAB and PAT in a timely fashion. To account for these two interim analyses and preserve an overall significance level of 0.05, procedures from Pockock were followed (2013; see Table 10.2) [91] and the final data analysis statistical significance level was adjusted to 0.022. Based on this stringent alpha value of 0.022 and estimated retention rate of 75% at 6-months, sample sizes were estimated to achieve 80% power (i.e., 116 dyads retained; 155 dyads recruited), 85% power (i.e., 132 dyads retained; 176 dyads recruited), and 90% power (i.e., 150 dyads retained; 200

Table 2
Child and parent outcomes measures assessed at baseline, 6-months and 12-months.

Domains Assessed	Child Measure Description[a]	Parent Measure Descriptions	Measurement Time Points			
			Base-line	3 months	6 months	12 months
Demographics	NA	Number of children in the home, race/ethnicity, age, marital status, education level, employment status, income, insurance type, subjective health literacy assessment of health literacy [73–75]	X			
Height and weight (BMI)	Measured by research staff using a calibrated digital Tanita scale and research-grade portable stadiometer (children are without shoes and in light clothing)	Measured by research staff using a calibrated digital Tanita scale and research-grade portable stadiometer (parents are without shoes and in light clothing)	X	X	X	X
Blood pressure	Measured by research staff with an automated oscillometric device (OMRON, Model:HEM-907XL), follows American Heart Association guidelines [76]	Measured by research staff with an automated oscillometric device (OMRON, Model:HEM-907XL), follows American Heart Association guidelines [76]	X		X	X
Waist measurement	Measured by research staff with tension-sensitive, non-elastic tape, and following measurement guidelines [77]	Measured by research staff with tension-sensitive, non-elastic tape, and following measurement guidelines [77]	X		X	X
Quality of life	23-item self-report assessment across four quality of life domains: physical, emotional, social, and school functioning [78]	5-item self-report assessment on quality of life, including overall health, physical health, mental health, and sleep [79]	X		X	X
Physical activity behaviors	8-item self-report assessment on number of times per week and minutes per time engaged in four types of activities: vigorous, moderate, mild, and strength training [80]	8-item self-report assessment on number of times per week and minutes per time engaged in four types of activities: vigorous, moderate, mild, and strength training [80]	X		X	X
Nutrition behaviors (fruits and vegetables, beverages)	6-items self-report on fruits and vegatables [81], and 8-item self-report on frequency and portion sizes of four beverage categories: water, sweetened juice, soda, sweet tea [82–84]	6-items self-report on fruits and vegatables [81], and 8-item self-report on frequency and portion sizes of four beverage categories: water, sweetened juice, soda, sweet tea [82,83]	X		X	X
Home environment	N/A	48-item self-report assessment related to meal preparation, physical activity equipment and resources, media equipment and use, and family practices and rules [85]	X		X	X
Health literacy	6-item self-report, objective assessment of health literacy [86–88]	6-item self-report, objective assessment of health literacy [86]	X		X	X
Program evaluation	Mixed-methods program evaluation and behavior change assessment	Mixed-methods program evaluation and behavior change assessment		X	X	X

[a] Note, self-reported measures are only assessed among children ≥8 years; except for the quality of life measure which was interview administered to children < 8 years of age.

dyads recruited). In sum, between 116 and 150 retained dyads (or 58 to 75 retained dyads per condition) would provide sufficient power to detect the a priori proposed effect size.

2.8. Data analysis

Quantitative data will be examined for the presence of outliers, violations of normality (for those continuous variables) and missing data. Major violations of normality will be corrected with an appropriate transformation procedure. Missing data will be handled multiple ways, including last-observation-carried-forward simple imputation, Bayesian multiple imputation, and the multiple imputation combined with Heckman model as proposed by Galimard and colleagues [92]. Qualitative data will be transcribed and reduced to meaning units (a phrase, sentence, or paragraph with a single meaning). Meaning units will be coded and organized into overarching themes [93–95].

2.8.1. Individual-level effectiveness and maintenance aims

In order to detect the BMI z-score reduction differences between the two conditions, multi-level mixed effect treatment models will be employed to control for errors of non-independence, heteroskedasticity caused by individual and family heterogeneity, and potential a priori determined covariates. Data from this trial is in longitudinal form, with four time point observations per participant (i.e., baseline, 3-, 6-, and 12-months). The child BMI z-score models will control individual child-level covariates and family-level covariates which are all determined a priori based on the literature on BMI z-score influencing factors. The family-level intercept will be allowed to be a random variable that vary by parent-child-dyads. The models also contain treatment group indicators, time period indicators and their interaction. To further control individual child-level unobserved heterogeneity that is time invariant, child-level fixed effects will be included. Cluster-robust standard errors will be employed. Sensitivity analysis will be conducted to examine the robustness of the mixed effect model across different random-effect distribution specifications (e.g., normal, finite mixture of normal etc.).

Exploratory analysis of the heterogeneity treatment effects (HTE) will also be conducted to inform future hypothesis generation. Individual attributes that may modify program effects include race, gender, child age, and parent health literacy status at baseline. Interactions (two-way and three-way) among those factors and time and group indicators will be added to the above multi-level mixed effect models to be tested. Even though this trial is not powered for the HTE analysis, all standard sensitivity analysis and reporting protocols will be followed using method proposed by Imai and Ratkovic [96].

Similar multi-level mixed effect models as in primary aim will be used to analyze secondary individual-level effectiveness and 12-month maintenance outcomes. This includes dependent variables for secondary child self-reported measures (e.g., quality of life, physical activity, nutrition), parent weight status, and parent self-reported measures (e.g., quality of life, physical activity, nutrition, and home environment). For discrete outcomes, appropriate link functions and distribution assumptions will be used in the modeling.

2.8.2. Secondary aims: reach, adoption, implementation, and capacity

Reach/representativeness will be analyzed following the recommendations of Glasgow et al. [20] Participation rate will be calculated as total enrolled sample divided by total number of eligible participants exposed to recruitment. To improve the comparison of representativeness, multi-level mixed effect logit models, similar to those presented above, will be used to create a summary effect size for differential characteristics by using the median effect size across the comparisons of demographic, health, and behavioral information of participants versus those declining participation. The median effect size will then be subtracted from the participation rate to provide a summary measure of reach. Adoption will be assessed descriptively in this trial and focuses on providing information on the organizations involved, the characteristics and missions of those organizations, and the degree to which they may be representative to other small town and rural areas interested in family-based obesity treatment programs.

Summary descriptive statistics reporting rates and cost of completion of in-person and IVR follow-ups will be computed for implementation indicators. Fidelity will be assessed as proportion of the intervention that is delivered as intended across intervention components based on IVR data and delivery agent fidelity checklists. These data will be reported descriptively and in concert with cost data. A concurrent mixed methods design will be used to collect quantitative and qualitative data collected on implementation and triangulated for interpretation [97].

For the capacity data, quantitative capacity dimensions will be analyzed using repeated measures ANOVA, accounting for differences between community and academic members. Capacity interviews will be transcribed verbatim. A minimum of two members will code meaning units from each transcript using NVivo (Version 11) and a hybrid inductive-deductive analysis approach to identify emergent themes related to capacity dimension [93–95]. A mixed-methods approach will be used to triangulate quantitative and qualitative capacity findings [97]. Also, guided by coalition process evaluation literature [50,51,98], meeting agendas/min, artifacts, and products of the CAB and PAT meetings will be systematically tracked, evaluated, and triangulated with both capacity and research outcomes.

3. Discussion

Despite the childhood obesity epidemic, as well as major health consequences of childhood obesity [1–3,5], sustainable solutions to treat childhood obesity remains a national challenge. This challenge is further magnified in medically-underserved communities that typically lack pediatric providers and often have limited clinical and community resources for implementing and sustaining childhood obesity programs. Though a number of childhood obesity treatment CER trials have emerged in recent years [99–102]; our CER trial is the one of the first known to be conducted in a micropolitan/rural setting and that applies an RCT design to examine the effectiveness of FBCO on child BMI z-score, while simultaneously evaluating the reach, adoption, implementation, and maintenance within existing clinical and community settings.

This underscores the focus of this trial on potential for dissemination, implementation and sustainability. Our approach includes features, such as defining and specifying an implementation strategy, with the information necessary for replication [103]. We also introduce methods for family accrual that could be used in other small communities and assess costs across implementation of recruitment strategies through program implementation—with a goal to provide actionable information for other small communities interested in adopting an evidence-based FBCO program. Finally, we include a sustainability action planning model that allows for further adaptation of the program based on the trial's results and identification of resources and infrastructure available for longer-term organizational maintenance of the program.

Perhaps unsurprisingly, our trial was strategically conceptualized, planned, and executed using participatory research approaches and a systems-based approach. As such, many of the previous, and more recent, comparative trials of FBCO programs may not generalize to communities where resources are limited and small numbers of families who could benefit from the programs are geographically dispersed. For example, recent work that compares high and low dose of intervention strategies in metropolitan areas—uses a low dose of 16 bi-weekly family sessions with a counselor working individual with each family [99]—a level of intensity that is higher than either of the conditions being tested in our trial and is unacceptable to both community organizations and families in the region. Therefore, this study will provide answers to important research questions generated by community

stakeholders and organizations, while concurrently addressing major gaps in the childhood obesity treatment literature. Most notably, it will inform whether adapted FBCO interventions can meet the needs of under-resourced small towns and rural areas in a way that allows for local ownership, implementation, and achieves reductions in child weight status.

There are numerous features of FBCO programs that may impact the likelihood of success in achieving and maintaining improvements in pediatric weight status. A few key examples include the grounding theoretical framework, overall intervention length, the number and duration of contacts, contact target (i.e., parent and child vs. parent only), structure of contacts (e.g., in-person vs. asynchronous technology-based), and type and structure of maintenance components. When examining the existing body of FBCO interventions, most of which occur in urban settings and few of which target low-income and minority children, those that include 26–75 contact hours or more are typically the most successful in reducing weight status [23]. However, there are a number of other individual-level outcomes that are less frequently considered when interpreting high intensity FBCO. For example, it is unclear if these FBCO are able to attract families that are representative of the targeted demographics. Also, high contact hours are often associated with less adherence among families, as families typically having scheduling and transportation difficulties [25,30,31]. Compounding adherence issues, is a trend for child weight status reductions to move towards baseline values, with a few exceptions [11,14], once a FBCO intervention is completed [34]. In the formative phases of planning this CER research, some CAB and PAT members identified longer-duration programs as potentially problematic for program participants, recalling many of the same issues that influence adherence in programs that have high contact, while others identify the need to offer high intensity and structured contacts to support families in changing and maintaining obesity-related behaviors. Process and outcome findings from our FBCO pilot trial in the targeted DRR further illustrated the challenges and opportunities in addressing these contradictory matters. More research is clearly needed that addresses these interrelated issues of effectiveness, adherence, and maintenance. That is, research efforts are need to identify the effective components of FBCO interventions that can be delivered at the lowest contact intensity for families, yet yield clinically relevant and sustained improvements in pediatric weight status [34].

This study also uses a community-engaged, systems-based approach to improve the likelihood of sustainability of one, or both, of the interventions locally—dependent on the effectiveness, implementation, and cost results [49]. The underlying proposition of our approach is that focusing on horizontal and vertical aspects of organizations across the community will result in improved capacity for childhood obesity program implementation and local ownership over sustainability decisions [55]. Operationally, this approach includes engaging key community organizations (horizontal community systems approach) and representatives from those organizations responsible for program implementation from recruitment, to program delivery, to retention as well as representatives from each organization who have decision making authority over the contribution of resources to sustain these activities [53,56]. This approach is also hypothesized to improve the characteristics of an innovation that have demonstrated predictive ability for adoption, implementation and sustainability [67,104]. Specifically, the systems-based approach has allowed for continuous matching and adaptation of intervention components based on the resources, expertise, and roles of each community partner—thus improving the compatibility of the interventions with local resources. Similarly, the adaptations completed on each of the interventions under investigation were completed using this systems-based approach and resulted in interventions that were less complex to implement relative to the more intensive original versions.

Finally, and most relevant for the current trial, is the ability of our approach to produce trialable interventions that can be piloted relatively easily across small cohorts of families. Importantly, this approach also allows for ongoing review and improvement of implementation processes and will subsequently provide a comparisons of the relative advantage between the two interventions and within context of services that were available in the community before the initiation of the trial [53–56,104]. Ultimately, the strengths of our study design and methods is the intentional balance between internal and external validity, as well as our the ability to synthesize and interpret findings across the RE-AIM dimensions, including both individual- and organization-level findings.

3.1. Limitations

Two main potential study limitations should be considered. First, our systems-based and CBPR approach may limit the generalizability of findings beyond the study region. Our study was purposefully designed and executed within the available resources and infrastructure of local health care and community organizations and with local community context in mind. While this may promote the likelihood of program sustainability in the DRR, it could also limit its application to other communities. Nonetheless, the applied capacity building processes and systems-based context may provide a useful planning and evaluation framework for other childhood obesity researchers and practitioners. Second, because of difficulties with study accrual in the first two cohorts, in the third and final cohort the eligibility criteria for children was expanded to 5–12 and an additional recruitment and program implementation site was added in the outlying county. Though we intend to conduct exploratory analyses, our study is not specifically powered to detect differences by participating children's age or study location. Importantly, previous systematic reviews have found little evidence of significant interaction between age of children participants and the treatment effect of multicomponent lifestyle interventions with parental involvement [105,106]. Also, while the age expansion influences the availability of self-reported data available from children, since children less than eight are less reliable at self-report and behavioral recall, it does not impact objectively measured BMI z-score in children (i.e., primary outcome). Finally, our mixed-methods reach and implementation process data will help identify any differences that exist between program locations and will be used in the interpretation of outcome findings.

4. Conclusions

Based on the current literature and our own preliminary data, our CBPR and systems-based proposed approach holds promise for establishing and translating efficacious FBCO interventions into practice in the health disparate DRR. We have intentionally designed a referral and recruitment process in partnership with two local clinical systems, who are the largest pediatric providers in the region, and with sustainability in mind. Health education staff employed by the City of Danville Parks & Rec are being trained to implement the FBCO interventions with high fidelity. The PAT members provide a social network for enrolled families and serve as a safety net to promote family engagement. Every aspect of this research is occurring within the existing community infrastructure in the DRR, with academic partners providing leadership and assistance for all research components including training, fidelity monitoring, and evaluation. Indicators of success will include reduced child BMI z-scores, the authentic engagement of multiple systems and stakeholders, and regional capacity to implement the FBCO programs as well as evaluate research evidence and ultimately integrate this evidence into sustainable practices. When local evidence from this trial is available to stakeholder and parents regarding differences in reach, adherence, effectiveness, and maintenance of the two programs (*i*Choose vs *Family Connections*), along with data regarding the potential for system sustainability, informed decisions can be made to help reduce childhood obesity disparities in the medically underserved DRR.

Likewise, the systems-based and participatory processes, such as stakeholder involvement with on-going program adaption and sustainability action planning, may be generalizable to other communities.

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