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Implementation of a Scalable Family-Based Behavioral Treatment for Childhood Obesity Delivered through Primary Care Clinics: Description of the Missouri Childhood Obesity Research Demonstration Study Protocol

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Abstract

Background: Significant gaps exist in access to evidence-based pediatric weight management interventions, especially for low-income families who are disproportionately affected by obesity. As a part of the Centers for Disease Control and Prevention's Childhood Obesity Research Demonstration project (CORD 3.0), the Missouri team (MO-CORD) aims to increase access to and dissemination of an efficacious pediatric obesity treatment, specifically family-based behavioral treatment (FBT), for low-income families.

Methods/Design: The implementation pilot study is a multisite matched-comparison group pilot of packaged FBT in pediatric clinics for low-income children with obesity, of ages 5 to 12 years old. The study is implemented in two Missouri pediatric primary care clinical sites, Freeman Health System Pediatric Clinics (rural Joplin) and Children's Mercy Hospital Pediatric Clinics (urban Kansas City). The design focuses on pragmatism through utilization of PRECIS (Pragmatic Explanatory Continuum Indicator Summary) domains, such as open eligibility criteria, limited follow-up intensity, reliance on medical records for creating a usual care comparison group data, and unobtrusive measurement of participant and provider adherence. The evaluation focuses on effectiveness as well as implementation outcomes and barriers to inform implementation scale up.

Conclusions: Findings from this study will advance both science and practice by providing novel and immediately useful information to families, health care providers, health care organizations, payers, and other state Medicaid plans by developing and optimizing evidence-based pediatric weight management treatment for implementation and dissemination in health systems to address health disparities among low-income populations most affected by overweight and obesity.

Keywords: childhood obesity; dissemination; family-based behavioral treatment; implementation; primary care

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Introduction

Approximately 41.5% of youth in the United States meet criteria for overweight or obesity,[1] and prevalence is higher among youth from low socioeconomic households and racial/ethnic minority youth.[2,3] Although there are evidence-based treatments for childhood obesity delivered in primary care settings,[4,5] low-income youth as well as racial/ethnic minority youth experience unique barriers to accessing quality care, including inadequate insurance coverage and high treatment costs.[6–8] As such, scalable childhood obesity interventions are urgently needed to address disparities in obesity among at-risk youth.[9]

To address this gap, the Missouri Childhood Obesity Research Demonstration (MO-CORD) project aims to increase access to and dissemination of family-based behavioral obesity treatment (FBT) for low-income families. FBT is designed to help parents and children establish sustainable eating and physical activity changes across multiple socioenvironmental contexts (*e.g.,* home, school, community, and work).[10] FBT is consistent with the US Preventive Services Task Force (USPSTF) recommendation of ≥26 hours of individualized intensive intervention delivered for up to 12 months.[11] Primary care offers an optimal setting for FBT delivery, as it capitalizes on the established relationship between primary care providers (PCPs) and families. Colocating interventionists within the primary care setting overcomes fragmentation of care and addresses provider time constraints and referral barriers. Furthermore, this delivery strategy dovetails with the obesity treatment benefit by the Missouri HealthNet Division of Missouri Medicaid published in March 2021 that covers intensive obesity behavioral counseling and medical nutrition therapy, thus setting the stage to scale FBT implementation across primary care.[12]

Missouri HealthNet Division's coverage changes will rectify lack of reimbursement as a major barrier to providing evidence-based treatment for obesity such as FBT for low-income families. However, for this change to achieve its desired effect, multiple barriers must be addressed. The delivery of FBT in primary care settings requires establishment of new roles to deliver the intervention. These interventionists then need to be trained, yet there is a lack of established and easily disseminated training and certification processes for FBT. PCPs also need training and guidance around diagnosis, referral, and coordination of care. In addition, there needs to be a better understanding of the contextual factors that promote uptake and sustainability of FBT in health care settings as well as the costs associated with implementation.

The MO-CORD project aims to address these barriers to care through three phases: (1) digitally package FBT behavioral health care interventionist training and intervention materials in a user-friendly scalable format with an emphasis on applying user-centered design methods; (2) conduct a multisite pilot implementation study in urban and rural pediatric primary care clinics involving establishment of new roles and training of interventionists and providers; and (3) develop a dissemination and sustainability plan for an optimized package incorporating lessons learned in the first two phases. This article describes the pilot implementation study protocol to accomplish the second aim mentioned.

Method

Study Design

The implementation research study uses a nonrandomized multisite matched-comparison design to pilot a packaged FBT, delivery by clinic-based interventionists, in seven pediatric clinics that primarily serve low-income families. The target enrolment in the FBT arm is 208 children 5–12 years old with obesity. A matched-comparison group will leverage historical controls selected from electronic health records (EHRs) of similar proximal clinics. The design focuses on pragmatism through utilization of Pragmatic Explanatory Continuum Indicator Summary (PRECIS) domains, such as open eligibility criteria, limited follow-up intensity, reliance on medical records for creating a usual care comparison group data, and unobtrusive measurement of participant and provider adherence.[13] The evaluation focuses on effectiveness as well as implementation outcomes and barriers to inform implementation scale up. The study logic model is shown in Figure 1. The Institutional Review Board approved the study (IRB ID #: 202103221-1070).

Specific Aims

The aims of the pilot implementation study within the MO-CORD project are as follows.

Conduct a pilot study to test a scalable implementation model targeting increasing capacity of PCPs to refer children to evidence-based treatment, establishing behavioral interventionists in primary care settings to deliver treatment, and increasing referrals and reach through multisectoral stakeholder engagement. We will assess the impact of our pilot implementation through two subaims:

Sub-Aim a. Evaluate *provider*- and *organizational*-level reach, adoption, implementation, and maintenance, including implementation contextual factors that may impact these outcomes.

Sub-Aim b. Evaluate *participant*-level acceptability, engagement, and effectiveness.

Participants

Multisite sample. The study will be implemented in two Missouri pediatric health systems in rural Joplin and urban Kansas City. Three and four pediatric primary care clinics will participate in the study within the Joplin and Kansas City health systems, respectively. The sites were chosen, in part, because they have active practice-based research networks for study recruitment and implementation. Both health systems play a leading role in local healthy eating/active living coalitions through which the pilot can be supported and promoted. The study population will consist

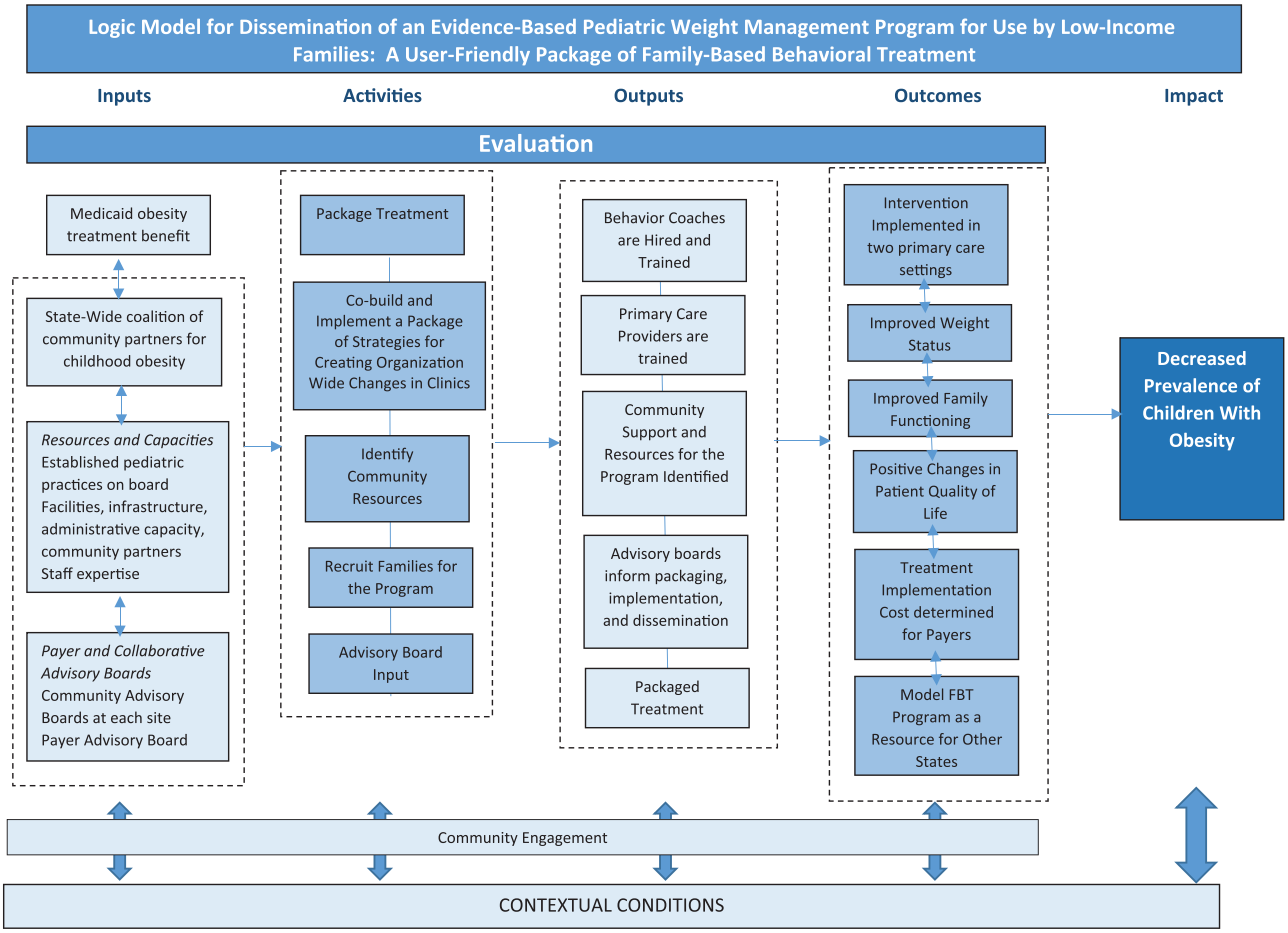

Figure 1. Logic model for dissemination of an evidence-based pediatric weight management program for use by low-income families: a user-friendly package of family-based behavioral treatment.

of low-income children with obesity of ages 5–12 years seen in an urban primary care clinic in Kansas City, MO (Children's Mercy Hospital's Pediatric Care Center—PCC) and rural primary care clinics (Freeman Health System) in Joplin, MO. Average characteristics of the two participating health systems over the past few years are presented in Table 1.

Recruitment and retention. Participant eligibility criteria include parent/caregiver 18 years of age or older and child of ages 5–12 years with BMI percentile ≥95th for age and gender, and enrolled in Missouri HealthNet Medicaid. Children will be recruited through referral by PCPs during any clinic visit (*e.g.*, well or sick) at the pediatric clinics in both Kansas City and Joplin. Implementation mapping was used to inform the

Table 1. Characteristics of the Participating Health Systems

Characteristic	Children's Mercy Hospital's Pediatric Care Center, *Kansas City, MO*	Freeman Health System, *Joplin, MO*
Physicians and nurse practitioners	54	12
Average patient visits per year	52,000	4500
Average eligible patients aged 5–12 years per year	9900	5200
Average percentage of patients 5–12 years with obesity	23% (2300)	19% (1000)
Average race/ethnicity of children with obesity	10% White 36% Black/African American 45% Hispanic 9% Other race/ethnicity	91% White 4% Black/African American 10% Hispanic 5% Other race/ethnicity
Average percentage of children with obesity on Medicaid	82%	37%

Averages are of patients seen in outpatient settings (e.g., well child care visits) in the participating health systems from the past few years.

development of strategies and tools for supporting referrals, as described later. Additional recruitment methods will include letters and calls to eligible patients identified through EHR database-generated lists and study promotion information disseminated through community partners. Multiple retention strategies are employed throughout the study to maximize participant retention throughout their 12-month intervention including flexible session scheduling, frequent contact, identifying and problem-solving barriers to attendance, use of telemedicine/virtual modalities for group treatment sessions, and expectation setting from first contact.

Intervention: Family-Based Behavioral Treatment

An overview of the development and packaging of the FBT can be found elsewhere.[14] The digital web-based FBT package includes content for training and certifying interventionists to deliver FBT, an interventionist portal to coordinate care with families and track progress, and a patient portal for children and caregivers to access digital resources and FBT materials to supplement their face-to-face group and individual sessions with interventionists. Over three decades of randomized-controlled trials have been used to develop, refine, and demonstrate the effectiveness of FBT, which provides a family-centered approach to help both caregivers and children build and establish lasting improvements in nutrition and physical activity and reductions in sedentary activity by applying self-regulatory skills, behavioral economics, and social learning theory principles to the practice of behaviors across multiple socio-environmental contexts (*e.g.*, home, school, community, and work).[10,15–18] Licensed behavioral health care interventionists (*e.g.*, social workers, professional counselors, registered dietitians, marriage/family therapists, and psychologists) serve as the FBT interventionists in this project. These interventionists are employed within each health system (1–2 per health system), their services are reimbursable by the Missouri Medicaid benefit, and can have other roles within the clinics (*e.g.*, behavioral health specialist).

Formative Work to Inform Integration of the FBT into Each Health System

We used the iterative and participatory approach of implementation mapping[19–22] to develop strategies and tools for supporting PCPs and other clinic staff to refer eligible patients to the program. This process is outlined in Table 2 and involved the creation of an implementation planning workgroup within each clinic and a series of meetings to discuss potential barriers to implementation and strategies for overcoming these barriers. The study team mapped the identified barriers to the constructs within the Consolidated Framework for Implementation Science (CFIR),[23] each of which have been linked to promising implementation strategies in previous research.[24,25] Although this mapping helped uncover broad implementation strategies to consider, the specifics of each strategy (*e.g.*, how, who) were based on discussion among the implementation planning workgroups. The resulting strategies and tools for supporting referrals included referral training workshops and ongoing check-in meetings, weekly reviews of upcoming visits to identify and flag eligible patients, a notification to PCPs and clinic staff within each eligible patient's electronic previsit checklist, a single-page bulleted referral guide with talking points, an informational handout for eligible patients, an individualized follow-up call with a program recruiter, and periodic summaries of referral rates for PCPs and clinics.

Table 2. Overview of Steps to Implementation Mapping Approach to Be Used in MO-CORD

Establish an implementation planning workgroup within each clinic.
Conduct a needs assessment to identify clinic-level barriers and facilitators for embedding the implementation effort into the organization/system.
Identify the determinants (behavioral, environmental, and other social determinants of health) of the key barriers, based on CFIR (*i.e.*, under which CFIR constructs do the barriers belong).
Identify potential implementation strategies for overcoming the selected barriers, using the list of strategies that have been mapped to CFIR
Operationalize each implementation strategy by adding specificity through workgroup discussion.
Create processes, documents, and other materials to guide implementation, based on the strategies identified.
Provide ongoing support to clinic implementation teams and adapt processes and materials as new lessons are learned.

CFIR, Consolidated Framework for Implementation Science; MO-CORD, Missouri team-Childhood Obesity Research Demonstration.

Evaluation Data Collection and Measures

Evaluation frameworks and overview. Study measures are organized by the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework,[26] which emphasizes reach, effectiveness, adoption, implementation, and maintenance in scaling up interventions. The *Sub-Aim a* organizational level outcomes address the reach, adoption, implementation, and maintenance components of RE-AIM; *Sub-Aim b* participant-level outcomes address acceptability and effectiveness. The *Sub-Aim a* outcomes have often been conceptualized as implementation outcomes given that they are key indicators of implementation success and intermediate outcomes in relation to treatment effectiveness.[27] MO-CORD will also use the CFIR[28] to guide the qualitative assessment of implementation contextual factors to uncover potential barriers and facilitators to reach, adoption, implementation, and maintenance. Study measures are presented in Table 3. Participant demographics (*e.g.*, gender, race/ethnicity) will also be assessed through questionnaire and obtained from EHRs from all pediatric clinic visits from the eligible clinics.

Table 3. MO-CORD Measures Organized by the RE-AIM Framework

Measure/construct	Level/unit of analysis	How used in analyses	Data source	Time point
Clinic-level measure (Sub-Aim a)				
1 Reach				
1.1 Percentage of eligible children who are (a) referred and (b) enrolled.	Clinics	Descriptive clinic-level outcome	Tracking records	End of study
1.2 Representativeness of those (a) referred and (b) who complete the study to (c) those eligible and (d) the statewide population	Clinics, state	Descriptive clinic- and study-level outcome	Existing data—electronic health records and health surveillance systems	End of study
2 Adoption				
2.1 Percentage of providers within the clinic who (a) ever and (b) regularly refer eligible patients to the program.	Providers, clinics	Descriptive clinic-level outcome	Electronic health records	End of study
2.2 Representativeness of participating clinics to all clinics in state	Clinics, state	Descriptive clinic-level outcome	Existing data—MO Primary Care Association	Baseline
3 Implementation				
3.1 Knowledge and weight bias	Interventionists	Descriptive	Surveys	Months 0, 3, 6, 12
3.2 Intervention fidelity and adaptations	Participants and interventionists	Participant-level predictor Clinic-level outcome	Audio recording audits and interventionist checklists and interviews	Ongoing
3.3 Costs (*e.g.*, Implementation training and intervention delivery)	Clinics, interventionists, and participants	Descriptive, and clinic-level and participant-level outcome	Electronic health records; website metrics; surveys	Ongoing
3.4 Implementation contextual factors	Clinics and health systems	Clinic-level predictor	Interventionist and medical director interviews	Postintervention
4 Maintenance				
4.1 Sustained delivery	Providers and clinics	Clinic-level outcome (also an implementation outcome)	Interventionist and medical director interviews	Postintervention
Participant-level measures (Sub-Aim b)				
5 Acceptability				
5.1 Acceptability	Participants (child and parent)	Patient-level outcome and predictor	Surveys	Postintervention
5.1 Engagement	Participants (child and parent)	Patient-level outcome and predictor	Tracking records and surveys	Ongoing
6 Effectiveness				
6.1 Percent overweight	Participants (child and parent), Matched comparisons for children	Patient-level outcome	Stadiometer (height) and scale Matched comparisons will be from electronic health records	Months 0, 3, 6, 12
6.2 Quality of life	Participants (child and parent)	Patient-level outcome	Surveys	Months 0, 3, 6, 12

RE-AIM, Reach, Effectiveness, Adoption, Implementation, Maintenance.

Reach and adoption (Sub-Aim a outcomes). Calculating reach helps to describe who is willing to participate in the intervention and how similar or different (*i.e.*, representative) participants are to those who are eligible but do not participate. A low reach value, based on the percentage of eligible children who are (a) referred and (b) enrolled, would indicate that greater efforts are needed to facilitate the identification and enrollment of participants. Indicators of representativeness can show whether specific population groups are being missed and how participation rates may translate to new geographic areas or settings with different populations. The MO-CORD team will calculate reach using data from the EHR of each participating health system, which involves tracking of patient eligibility, referrals, and enrollment. Since all seven sites are considered adopters, MO-CORD will calculate levels of adoption within each clinic, defined as the proportion of providers within the clinic who (a) ever and (b) regularly (*e.g.*, ≥50% of the time) refer eligible patients to the program. The representativeness of the adopting clinics will be captured by comparing their clinic and patient characteristics with statewide data from health surveillance systems such as the MO Primary Care Association.[29]

Implementation (Sub-Aim a outcomes). Interventionist knowledge and skills related to FBT delivery will be assessed using a 20-item questionnaire we developed for a previous study, before and after training of the interventionists. Fidelity to essential intervention components will be measured using regular supervision checklists completed by the study team and self-reported adherence completed by interventionists after each session. Adaptations to nonessential intervention components will be measured using postintervention interviews with interventionists.

Implementation costs (Sub-Aim a outcomes). We will assess the costs to implement FBT inclusive of labor and nonlabor costs.[30,31] We will use a societal perspective that includes providers, participants, and payers (insurers); each of those groups will also be reported separately.

Training. We will use a microcosting approach,[32] combining time spent on each component of FBT with wage/salary data including fringe benefits. We will assess FBT interventionists' time spent receiving FBT training using website usage metrics (*e.g.*, logins and time spent using the website) and self-report survey of their time completing the web training and any additional training activities.

Delivery. During FBT delivery, we will collect EHR data on number of visits, who delivered the session, and when included in the note, the duration of the session. However, since additional time may be incurred for FBT that is not part of the record or bill, we will compare this with providers' self-reported time and adjust as necessary. As FBT will be reimbursable in Missouri, we will collect Medicaid claims data to account for provider and facility fees through the University of MO-Columbia Center for Health Policy, which contracts with MO Medicaid to provide this service and has agreed to assist with the project. We will continue to track time FBT providers spend using the treatment website for ongoing training and delivery support. Furthermore, we will assess the number of hours FBT providers, medical providers, and clinic administrators spend engaged in nonresearch implementation activities, such as participating in meetings to establish an implementation plan for the clinic and completing recertification, and any in-kind services that are provided to support implementation, derived through brief survey. Finally, participants will report through questionnaire any costs incurred as a result of treatment (*e.g.*, buying a scale). Costs to maintain the FBT website will be collected from the vendor.

Implementation contextual factors (Sub-Aim a antecedents). Implementation contextual factors will be assessed postintervention using qualitative interviews of interventionists and clinic-level medical directors/administrators based on the CFIR structured interview guide.[28] These interviews will help uncover whether remaining implementation barriers exist and/or additional implementation strategies that may have been used within each clinic to support success around referrals and intervention delivery embedded within the existing health system.

Maintenance. The likelihood of sustained delivery of the intervention within each clinic will also be assessed during the postintervention qualitative interviews.

Acceptability (Sub-Aim b outcomes and antecedents). Participant engagement and acceptability will be monitored by tracking session attendance and assessed using the Therapeutic Alliance Scale.[33]

Effectiveness (Sub-Aim b outcomes). Children's and parents' height and weight (measured objectively) and quality of life will be assessed by FBT therapists at baseline, end of treatment, and 6 months follow-up. The primary effectiveness outcome will be change in child's percent overweight from baseline visit to post-treatment assessment, where child's percent overweight is calculated as

$$\text{Percent overweight} = \frac{\text{child's BMI} - \text{the median BMI [for the child's sex and age]}}{\text{median BMI}} \times 100$$

Median BMI for the child's age (in months) and gender is based on norms defined by Kuczmarski et al.[34] and

available from the Centers for Disease Control and Prevention. Change in parent/caregiver weight is also a primary outcome of the implementation study.

Secondary outcomes include participant quality of life assessed using the SF-12 and Sizing Them Up for adult and child quality of life, respectively.[35,36] Adherence to diet, physical activity, and behavioral skills will additionally be assessed through caregiver report using the Family Nutrition and Physical Activity measure.[37]

Matched comparisons for evaluating changes in percent overweight. Each health system's EHR database will be used to retrospectively identify at least 1 comparison child for each study participant (total comparisons $n = 208$). The historical control match group data are drawn from the EHR at both external clinical sites from participants not eligible for the Medicaid benefit. Child-participant data are obtained from all pediatric clinic visits from the eligible clinics. Comparisons will be matched to the study participants based on age, gender, race/ethnicity, and percent overweight.

Statistical Analysis Plan

For *Sub-Aim a*, all data are at the clinic level ($N = 7$ clinics across the two sites). Each clinic's scores on reach, adoption, implementation cost, and maintenance, and each interventionists scores on implementation knowledge and fidelity, will be summarized descriptively. The implementation contextual factor (CFIR) interviews will be transcribed and coded using the established coding procedures developed by the CFIR team, which will involve creating memo summary for each CFIR construct and coding its presence ($= 1$)/absence ($= 0$) and valence rating (-2 to 2, strongly negative to strongly positive).[28] Ratings will be compared across clinics and between clinics with higher vs. lower reach, adoption, implementation cost, and maintenance scores, and between interventionists with higher vs. lower implementation knowledge and fidelity scores (based on sample distributions). Narratives and quotations from the interview content will be used to provide more depth of information to guide future implementation efforts.

For economic evaluation, we will aggregate the labor and nonlabor cost data to measure the costs of implementation. These data will also be combined with effectiveness (below) to report costs per outcome, or average cost-effectiveness ratios. Labor costs from implementing and sustaining the intervention will be captured by deriving a per-hour salary rate including fringe benefits for each provider or organizational leader in the study. Total labor costs are the product of hourly rates plus fringe and the time spent engaged in each implementation activity. For costs measured over multiple years, an annual 3% discount rate will be applied. For FBT sessions in which the duration of the visit is unknown, we will impute the average session duration for that FBT provider or the clinic. Once total costs are calculated for the full sample of participants, we will calculate a per family cost of implementation and the cost-effectiveness per child, parent, and family to achieve changes in weight. We will assess the robustness of our results by conducting sensitivity analyses to evaluate the costs and cost-effectiveness if aspects of implementation were varied (*e.g.*, level of training of the FBT provider).

For *Sub-Aim b*, our sample size of 208 children in the FBT arm with 208 (or more) in the historical matched-comparison cohort is sufficiently powered to test the hypothesis that FBT achieves a significant and clinically meaningful reduction in weight. Our estimated change in the FBT group begins with a review of seven studies.[10] To ensure the study is well powered, we assume a 1% weight loss in the historical control matched group. An intraclass correlation was included in power calculations to account for the delivery of the FBT intervention in a group setting. *A priori* matching or stratification is not possible due to the pragmatic nature of this trial; however, the analyses take into account the intervention group as a random effect in the clustered design. This study is powered at 90% to detect a reduction in excess weight in children between 7% and 7.5% to make sure the study is well powered.

To evaluate effectiveness, we will use a mixed effect linear model to estimate the percent weight change in the children. These analysis groups will use the historical matched controls and be based on group level differences. Subanalysis will be done on the treatment group only since there are dyadic data between parent and child. Additional dyadic analyses will be conducted, on the treatment group only, to determine whether more information is obtained by modeling both responses.[38] Analyses of the relationship between child and parent dyads will use linear mixed models with multiple levels. This analysis will primarily be within-subject comparisons and, in addition to percentage weight loss, includes quality of life. This study will also investigate possible differences in subgroups, such as gender and race, within the treatment group. Intent-to-treat analysis will be used so all participants will be used in the models. Sensitivity analysis will be conducted to determine how the missing data affect the results, using both completers and Markov Chain Monte Carlo algorithm methods.

Discussion

This project aims to increase accessibility and scale up of FBT, an evidence-based pediatric obesity treatment, among low-income families. The evaluation will provide critical insight into the challenges of implementing FBT within diverse community settings and approaches for overcoming these challenges. By testing this care delivery model in two distinct contexts—a rural and urban setting—this study will be able to advise future efforts to deliver care in diverse communities across the United States and reach more children in need.

The MO-CORD project is the first study of its kind to evaluate the implementation of a digitally packaged FBT

delivered by interventionists embedded within a pediatric primary care setting. By capitalizing on the established relationship between providers and families, primary care offers an optimal setting for FBT delivery, reducing fragmented care that can occur through multiple providers and offices. This study will provide insight into the organizational, provider, and community connectedness factors underlying adoption of an evidence-based pediatric obesity treatment for low-income families and the relationship between patient and provider fidelity to the treatment protocol; other patient, provider, and organizational factors; and clinical outcomes. In addition, implementation in both a rural and an urban clinic will allow for evaluation across diverse settings and contribute to more rapid translation of FBT into primary care practices resulting in a more immediate public health impact than traditional effectiveness studies.[39,40]

The study is innovative in its key focus on sustainability and replicability/scale up through existing health care mechanisms designed to serve low-income families. Importantly, all children with obesity enrolled in Missouri Medicaid will be entitled to the timely benefit that covers behavioral obesity treatment. Insights from the implementation of the provider trainings can inform efforts to develop a workforce for delivery of this new benefit beyond the pilot sites. This study will also be the first to evaluate the costs associated with FBT implementation in pediatric clinics, thereby providing critical information for payers to improve their decisions regarding reimbursement for obesity treatment. The MO-CORD project will further equip other private and public payers across the United Sates with preliminary evidence on the extent to which the Medicaid reimbursement model is cost-effective and sustainable.

Conclusion

Data from this study will lead to the creation of a sustainability and dissemination plan. We will leverage established community and state advisory bodies who have prioritized childhood healthy weight to directly inform the scalability and sustainability of the packaged FBT. In this way, this project will serve as a model for other states to implement cost-effective evidence-based care for FBT with multisector supports that meet the needs of our evolving health care system.

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Author Disclosure Statement

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