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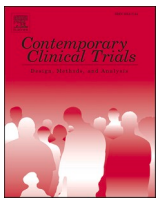

A pragmatic trial of a family-centered approach to childhood obesity treatment: Rationale and study design

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ABSTRACT

Background: Family-based behavioral treatment (FBT) is an effective intensive health behavior and lifestyle treatment for obesity reduction in children and adolescents, but families have limited access. The purpose of this randomized, pragmatic, comparative effectiveness trial was to examine changes in child relative weight in a 12-month, enhanced standard of care (eSOC) intervention combined with FBT (eSOC+FBT) vs. eSOC alone.

Methods: Children aged 6 to 15 years with obesity, and their primary caregiver, were recruited from primary care clinics. Families were randomized 1:1 to eSOC, a staged approach led by the primary care provider that gradually intensified dependent on a child's response to care and aligns with the American Medical Association guidelines, or the eSOC+FBT arm, which included regular meetings with a health coach for healthy eating, physical activity, positive parenting strategies, and managing social and environmental cues. Both treatments align with the 2023 American Academy of Pediatrics clinical practice guidelines. Assessments occurred at baseline, midpoint (month 6), end-of-intervention (month 12), and follow-up (month 18). Primary outcome was change from baseline to 12 months in child percent overweight (percentage above the median body mass index in the general US population normalized for age and sex). Secondary outcomes were parent weight, child psychosocial factors, heterogeneity of treatment effects, and cardiometabolic risk factors. Exploratory outcomes assessed reach, effectiveness, adoption, implementation, and maintenance.

Conclusion: This pragmatic trial will generate evidence for the comparative effectiveness of implementing two guidelines-based approaches in primary care for obesity reduction in children and adolescents.

Trial registration: ClinicalTrials.gov Identifier: NCT03843424

Childhood obesity remains an urgent public health concern, with one in five U.S. children between the ages of 2 and 19 having obesity [1,2]. Youth with obesity are five times more likely to have obesity as adults compared to peers with healthy weight [3]. Pediatric obesity contributes to cardiometabolic risk [4], poor sleep [5], type 2 diabetes [6], decreased quality of life [7], and depression [8]. These negative health outcomes are even more prevalent among the uninsured and underinsured [9] and among children who are historically marginalized [10], further exacerbating health disparities.

The 2023 American Academy of Pediatrics (AAP) Clinical Practice Guideline (CPG) for the Evaluation and Treatment of Children and Adolescents with Obesity recommended intensive health behavior and lifestyle treatment (IHBLT) programs as an effective approach that should be offered to all children and adolescents with obesity [11]. IHBLT delivers at least 26 h of family-based counseling over a 3- to 12-month period for children 6 years and older with overweight and obesity, a recommendation also consistent with the 2017 U.S. Preventive Services Task Force (USPSTF) guidelines [12]. Family-based

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behavioral treatment (FBT) meets these recommendations and has been found to effectively reduce child percent overweight by up to almost 20% [13]. FBT programs are comprehensive and include behavioral modification, positive parenting practices, environmental modification, and a focus on nutrition and physical activity counseling [14].

The 2023 AAP CPG also endorsed the role of the primary care provider (PCP) to deliver counseling on nutrition and physical activity (referred to as "enhanced standard of care" [eSOC] for this study). In recognition that many PCPs do not have access to IHBLT, the AAP CPG recommends that pediatricians and other pediatric healthcare providers increase the intensity of weight management support by connecting families with resources to support nutrition and physical activity based on the availability of local dietitians and community programs. This approach aligns with the prior 2007 American Medical Association (AMA) staged approach that begins with prevention counseling by the PCP and gradually escalates as indicated to structured meal and physical activity plans, and then finally to IHBLT programs, medication, and surgery when available and when prior efforts fail to produce weight loss [15].

There remain gaps in the dissemination and implementation of FBT programs in primary care settings. The first gap is the need for primary-care feasible interventions [16]. While primary care locations are promising for the dissemination of feasible and efficacious treatments [17], more information is needed on their consistency with national recommendations for pediatric weight management. Further, telehealth is a growing option but remains understudied as a mode to deliver eSOC or IHBLT. The second gap is in understanding FBT outcomes among racially and ethnically diverse samples. Despite differences in prevalence of obesity among White, Hispanic, and Black children [10], less research is available on the treatment effects of FBT among these groups [18]. Some FBT trials have found no differences in weight outcomes, following treatment, for Hispanic versus non-Hispanic participants [19], but less is known about differences among White versus Black children [20]. A third gap is potential differences in treatment effects between girls and boys [21]. Research between adult men and women suggest differences in reductions in weight and adiposity [22], treatment adherence [23] and participation [24]. Less is known among pediatric samples about these important sex-specific differences. Finally, FBT programs delivered in specialty care or academic research settings have benefited the caregiver [25,26], but FBT delivered in a pediatric primary-care setting for adult and child weight loss remains under-evaluated though initial results are promising [18]. The current study aimed to address these important gaps in the evidence [16].

The Treatment Efforts Addressing Child Weight Management by Unifying Patients, Parents, and Providers (TEAM UP) study was a randomized, pragmatic, comparative effectiveness trial that examined changes in child relative weight in a 12-month, eSOC with FBT (eSOC+FBT) vs. eSOC alone, both delivered in primary care. It was hypothesized that children and their parents/caregivers who received eSOC+FBT would have greater reductions in percent overweight compared to those who received eSOC alone. Secondary aims of the study included: 1) examine if children who receive the eSOC+FBT intervention will improve psychosocial factors relative to children who receive eSOC alone; 2) examine the heterogeneity of treatment effects (HTE) across participant subgroups; and 3) examine improvements in standard clinical and laboratory assessments of cardiometabolic outcomes. An exploratory aim of the study was to conduct process evaluations to assess RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) [27] domains across participants, providers, and practices.

1. Methods

1.1. Study design

Participants were randomly assigned to 12-months of eSOC alone (n = 376 child-parent/caregiver dyads) or eSOC+FBT (n = 354 dyads), with primary child/parent measurements obtained at 6 (midpoint), 12 (end), and 18 (follow-up) month intervals. All participating children and parents/caregivers received eSOC delivered by a PCP. To examine the feasibility of implementing IHBLT within primary care settings, coaches delivered FBT and provided on-going care coordination with the child's PCP.

1.2. Partner and family engagement

A Family Advisory Board allowed the study team to engage with families (non-study participants) throughout the development of study materials, active intervention, and dissemination of results. Parent focus groups were conducted to ensure feasible and understandable treatment components [28]. A board of research and clinician scientists, the Evidence-Based Advisory Board, advised on implementation of evidence-based practices. The Provider Advisory Board, composed of pediatricians, family medicine physicians, nurse practitioners, dietitians, and behavioral counselors, advised on eSOC and FBT provider training, patient recruitment, intervention implementation in the clinic setting, and continuity after the study ended. The Payer Advisory Board guided the dissemination plan by defining indicators related to study outcomes that support advocacy for reimbursement of obesity services. Members of the Advisory Boards are listed in the Acknowledgements.

1.3. Participant recruitment and screening

All study procedures were approved by the Washington University in St. Louis Institutional Review Board (IRB), which served as the single IRB. Study staff were certified to the same protocol and manual of procedures across all sites; certification included written assessments and direct observation by lead data collectors during assessment visits. Families were recruited from clinical practices in primarily urban and suburban sites including greater Baton Rouge and greater New Orleans, Louisiana; Rochester, New York; greater St. Louis area and Columbia, Missouri extending into rural areas of the state; and suburbs of St. Louis in Illinois. This was a convenience sample with a target to recruit 50% non-white families to ensure diversity. Specific efforts were made a special focus on recruiting Black families, Hispanic families, and families insured by Medicaid. For example, some clinical practices were enrolled because of their high proportion of minority and Medicaid insured patients, and photographs and videos used in recruiting materials included people of diverse racial and ethnic backgrounds. Because of the pragmatic nature of the trial, the trial used broad eligibility with minimal exclusion criteria (see Table 1). The term parent/caregiver refers to the targeted adult who regularly attended treatment with the participating child.

Recruitment strategies included face-to-face recruitment where the PCP referred interested families to study staff; electronic medical records (EMR) queries to identify eligible families who were approved by the PCPs to be contacted; and general advertisements in practices/clinics, on provider websites and social media, and in targeted social media advertisements.

Parents/caregivers completed a brief web screening to determine initial eligibility. Parents who were preliminarily eligible were contacted to complete the Phone Screen, which involved a brief study overview and additional eligibility questions.

Following this, the Screening Visit (SV) and Baseline Visit (BV) were scheduled. Study measurements are detailed in Table 2. Parent/caregiver consent and child assent for the study was obtained in stages prior to the respective data collection: first for the web and phone screens, then for the screening visit and full study. At the SV and BV, height and weight were measured, and participants completed questionnaires. A lifestyle interview was administered at SV to identify potential barriers to study participation. The interview ensured participants understood study protocol and were willing/able to take part. Following this visit, if

Table 1
Eligibility criteria for the TEAM UP trial.

Inclusion Criteria (Child and Parent/Caregiver)	Exclusion Criteria (Child)
Child Inclusion Criteria:	**Child Exclusion Criteria**
• BMI percentile ≥95th for age and sex • Aged 6–15 years • Comfortable speaking English language • Able to provide written or verbal (based on age and preference) informed assent • Willing to change eating behaviors, physical activity, and/or weight • Patient of a participating clinic • Able to participate in scheduled sessions	• Families who plan to no longer have the child be a patient of any participating clinic during any point in the 18-month study period • Families for whom the PCP or site Principal Investigator (PI) thinks the study and/or intervention is clinically/medically inappropriate (e.g., more than mild developmental delay, or emotional or cognitive difficulties, if the PI/PCP believes these factors will interfere with study/intervention participation) • Families in whom the parent or child exhibits purging behavior and/or other significant eating disorder symptomatology • Children with chronic conditions or on medications that substantially impact or interfere with growth, appetite, weight, or physical activity participation
Parent/Caregiver Inclusion Criteria: • Aged ≥18 years • Comfortable speaking and reading English language • Child resides with the participating parent/caregiver ≥50% of the time	

the family remained interested and deemed eligible, they were randomized for enrollment. After randomization, the intervention commenced, and families were asked to complete assessment visits at month 6 (mid-point), month 12 (end-of-intervention), and month 18 (follow-up).

Study data were collected and managed using Research Electronic Data Capture (REDCap), a secure, web-based application design to support data capture for research [29].

1.4. Randomization and blinding

The TEAM UP Data Coordinating Center (DCC) utilized the REDCap randomization module to randomly assign families to either eSOC or eSOC+FBT. Randomization was blocked within clinical practice using random block sizes and stratified by both sex and race (white and non-white). Data collection staff were blinded to the greatest extent possible; unblinding occurs rarely, e.g. when families unintentionally reveal their condition. Investigators not directly involved in supervising treatment delivery or providing medical oversight were blinded. Participating families were aware of their assignment, as were providers delivering treatment.

1.5. Description of enhanced standard of care (eSOC)

All enrolled participants received eSOC, which was administered by the child's PCP following the AAP Obesity Clinical Decision Support Chart and Next Steps resource manual [30–32]. Prior to recruitment, participating PCPs were trained to the AMA pediatric obesity treatment recommendations [33] that account for clinical practice capacity, motivation of the family, child's physical and emotional development, and weight status [33]. This training, organized by the AAP (see Appendix), occurred during a multisession tele-education learning collaborative, with curriculum developed by the AAP Institute for Healthy Childhood Weight in conjunction with the advisory groups. To build capacity among PCPs to deliver best-practice, specialized care, the Project Extension for Community Healthcare Outcomes (ECHO®) model was used to connect providers with experts and allow for case conferencing and peer support [34]. In 2019, the initial clinical practices and providers participated in a live telehealth training of 8 sessions over 8 h, with a requirement that providers attend at least 6 of the 8 sessions to participate as TEAM UP PCPs (20- to 30-min didactic portions followed by 30-min case conferencing). Clinical practices and providers who joined the trial after this initial series were provided access to the filmed recordings and watched at least 6 of the 8 sessions. After the core sessions, from 2019 to 2023, providers were offered ongoing monthly (and then bimonthly) optional 1-h sessions as a group with AAP faculty and invited guest lecturers delivering didactic information related to obesity treatment and facilitating case conferencing. Providers engaged in a range of trainings based on their availability and interest.

In accordance with AMA guidelines, children initially received in-office (or telehealth, particularly during the COVID-19 pandemic) counseling from their PCP, and then based on response and motivation/readiness for change, received a higher level of care as needed. Following the AMA guidance on the staged approach to pediatric obesity treatment (see Fig. 1) and depending on family availability/interest and child's response to treatment, providers were asked to offer at least 6 but up to 21 eSOC visits over the course of the 12-month intervention at the provider's discretion and family's schedule. At these visits, providers assessed weight progress, child/family motivation and readiness to change; problem solved barriers to weight loss; and implemented dietary and physical activity goals and strategies to support behavior change [33].

1.6. Description of family-based behavioral treatment (FBT)

In conjunction with the eSOC and ongoing medical monitoring offered by the PCP, the families assigned to eSOC+FBT also engaged in FBT. FBT is a rigorously tested, multicomponent intervention that targets diet, activity, behavioral skills, parenting, and facilitation of support in family and peer environments [35–40]. Coaches, who were existing practice staff wherever possible, were trained in the delivery of FBT (see Appendix). Following an initial workshop, coaches received ongoing training and supervision using the ECHO® model and methods, similar to the approach for eSOC providers described above, as well as weekly individual sessions with a study staff member experienced in FBT. The Training and Fidelity Core (TFC) at Washington University in St. Louis, MO provided oversight of supervisors for consistency across sites. Supervisors met as a group weekly to discuss areas of concern; they also performed monthly fidelity rating calibrations of audio recordings to ensure that consistency was maintained.

FBT included: 1) the Traffic Light Eating Plan, (i.e., a family-friendly method of color-coding foods to guide families toward the goal of consuming more low energy dense, high nutrient dense foods (GREEN), and fewer low nutrient, high energy dense foods (RED)). Children and their parents were provided individualized calorie goals and goals to reduce RED food intake and increase GREEN food intake; 2) the Traffic Light Activity Program also utilizes RED, YELLOW, and GREEN labels to categorize activities of different levels of caloric expenditure, to help increase physical activity and reduce sedentary behaviors. Parents and children were taught skills to decrease RED activity and increase GREEN activity; 3) behavioral strategies and parenting techniques, including stimulus control (e.g., parents were taught how to modify the home to create a healthier shared family environment), self-monitoring, goal setting, problem-solving, and finding substitutes for highly reinforcing foods. Parents were trained to use praise and positive reinforcement to shape and maintain their child's healthy behaviors, as well as how to engineer healthy eating, activity, and sleep routines. Parents were encouraged to make changes in the same behaviors as their children, and to model these healthy behaviors and attitudes about behavior change; and 4) social facilitation focused on helping parents and children build supportive family and peer environments conducive to healthy weight-control behaviors and body esteem. Children were also coached in how to manage negative peer interactions (e.g., teasing) that hinder healthy behaviors and how to improve their ability to seek healthy peer-based alternatives to sedentary activities [38,39,41–43].

FBT visits began as soon as feasible following the BV and concluded

Table 2
Data measurement and collection schedule.

Domain	Measurement (for Whom)	# of items	Respondent[a]	Phone Screen[b]	Screen Visit	BV	M1.5	M6	M12	M18
Relative Weight	Height	-	Child	X	X	X		X	X	X
		-	Parent		X					
	Weight	-	Child	X	X	X		X	X	X
		-	Parent		X	X		X	X	X
Mental Health	Eating Disorder Symptoms (Parent/Child)	6	Parent		X			X	X	X
		6	Child		X			X	X	X
	CESD-10 + 2 ASQ (Child)	12	Child		X					
	PHQ-9 (Parent)	9	Parent		X					
	GAD-7 (Parent)	7	Parent		X					
	PSC-17 (Child)	17	Parent		X					
Family	CHAOS (Family)	15	Parent		X					
	FNPA (Family)	20	Parent			X		X	X	X
Quality of Life	Experiences with Teasing (Child)	12	Child			X				
	Coping with Teasing (Child)	7	Child			X		X	X	X
	Sizing Them Up (Child)	22	Parent			X		X	X	X
	Pediatric Quality of Life (Child)	23	Child			X		X	X	X
	SF-12 (Parent)	12	Parent			X		X	X	X
Motivation	Autonomy Support (Parent)	3 + 3[c]	Parent			X	X	X	X	X
	Self-Regulation (Parent)	8	Parent			X		X	X	X
Late Study Measures	Change in Health History	20	Study Staff					X	X	X
	Acceptability	12	Parent					X	X	X
		8	Child					X	X	X
	Medical Record	-	Study Staff							X
Other	Clinical Interview (Parent/Child)	34	Parent/Child		X					
	Demographics (P/C)	29	Parent		X					

[a] Yellow indicates reporting by parent/child and blue indicates information collected by study staff.
[b] PCP/Provider authorization to participate was needed between the Phone Screen and the Screening Visit.
[c] eSOC + FBT families were asked 3 additional questions pertaining to their FBT coach.

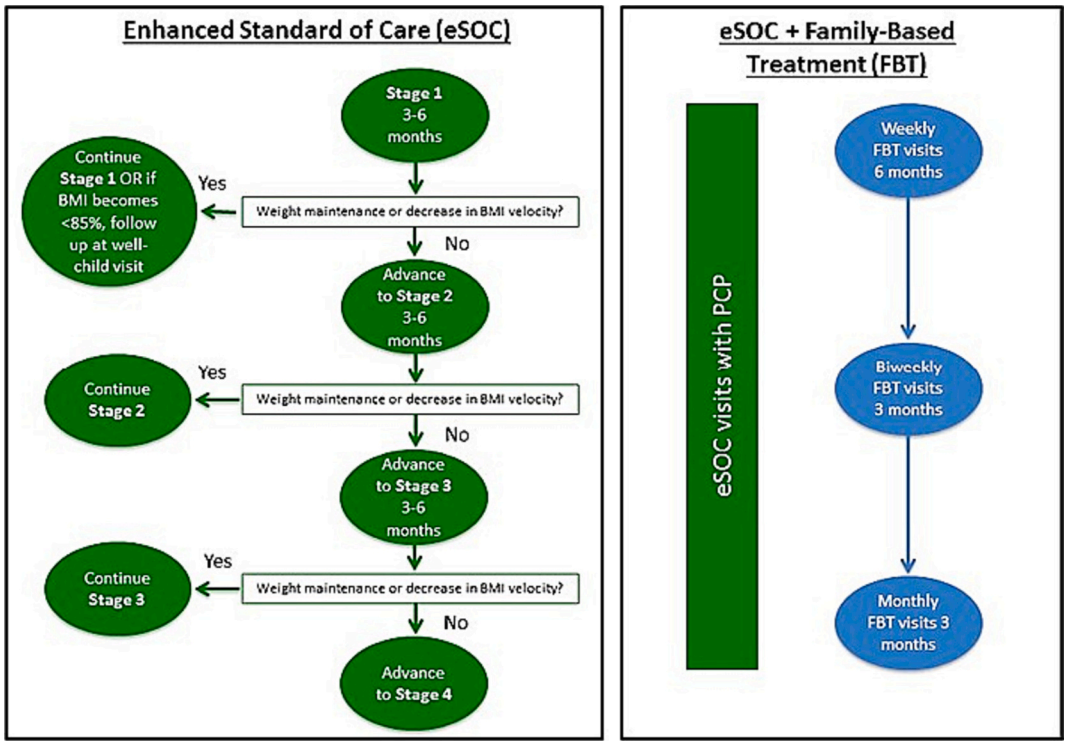

Fig. 1. Flowchart illustrating how participants progressed through eSOC and eSOC+FBT.

at the end of the one-year treatment window. FBT began with weekly visits for six months, then transitioned to biweekly FBT visits for three months, then monthly visits for three months, as feasible for the family. Families were seen in individual sessions, for approximately 30 to 50 min, that incorporated taking parent and child weights, review of eating and activity self-monitoring logs, review of weight change and connecting it to energy-balance behaviors, problem-solving and goal setting for the next meeting in relation to behavior change targets, and review of treatment handouts. FBT coaches used a "dashboard" to track information from their sessions in REDCap to manage treatment, charting, delivery, and oversight/supervision. This information was also used to calculate dose, fidelity, engagement, process data, and parent/caregiver and child behavioral changes. For care coordination, coaches communicated to the child's PCP at least quarterly including patient progress, attendance, and any medical concerns.

1.7. Study adaptations for COVID-19

The COVID-19 pandemic set off a national public health emergency in early 2020; it interrupted the study progress and constrained (in many cases closed recruitment and enrollment) study-related activities, with additional disruptions over time due to virus variants. The study adapted to these circumstances and resumed activities under COVID-19 precautions and safety protocols. Adaptations included offering flexibility for training/onboarding of PCPs to deliver eSOC; re-programming of REDCap to allow for a fully remote delivery from screening through end of study; training study personnel to utilize remote methods (online, video, phone) for treatment delivery, enrollment, and data collection; and purchasing and providing study data collection equipment (digital scale, metal tape measure, and carpenter's square) to all participants for at-home height and weight measurements.

1.8. Primary and secondary outcome measures

The primary outcome measure was child percent overweight, defined as $\frac{child's\ BMI - the\ median\ BMI\ [for\ the\ child's\ sex\ and\ age]}{median\ BMI} \times 100$. Median BMI was normalized for child age and sex based on nationally representative data. [44,45] Secondary measures are listed below. See Table 2.

1.9. Physical measurements

Study-provided equipment, as described above, was mailed to all participant homes, so that families were prepared should an assessment need to be completed remotely. A validation study of 37 families within the TEAM UP study indicated high concordance and reliability with no significant differences in height or weight collected remotely vs. in-person [46]. Physical measurements were performed on child (primary outcome) and parent (secondary outcome).

Height (in-person). Trained staff measured participants' height twice to the nearest 0.1 cm using a Seca 213 portable stadiometer or equivalent in the PCP office, with a third measurement if first two differed by >0.3 cm.

Height (remote). Families were sent written instructions with an instructional video prior to assessment for remote height measurements. Height information was collected following Centers for Disease Control (CDC) guidelines [47], with study staff observing via videoconferencing (exceptions were made occasionally, when families had faulty Wi-Fi or video equipment). Parents/caregivers were instructed to collect height twice to the nearest 0.1 cm for their child using the provided materials and instructions, with a third measurement if first two differed by >0.3 cm.

Weight (in-person). Trained study staff measured participants' weight twice without shoes to the nearest 0.1 kg using a Seca 876 medical digital scale in the PCP office, with a third measurement if the first two differed by >0.3 kg.

Weight (remote). Using the CDC guidelines for recording weight from home [47], participants used an Etekcity scale (model No. EB4473C). Weight was measured two times, with a third measurement if the first two differed by >0.1 kg. Remote weight measurements were observed by trained staff via videoconferencing whenever possible, with a third measurement if the first two differed by >0.3 kg.

1.10. Child and parent report

Acceptability. Children and parents/caregivers were asked to self-report on the acceptability of the intervention using the validated 8-item Client Satisfaction Questionnaire [48].

Eating Disorder Screening and Monitoring. Trained staff administered this 6-item interview-style measure assessing dietary restraint, weight and shape concerns within the last 28 days, and loss of control eating episodes and purging behaviors within the last 3 months, adapted from the validated Eating Disorder Examination Questionnaire [49,50].

1.11. Child report

Child Depression and Suicide Screening. The 10-item *Center for Epidemiological Studies Depression Scale Revised (CESD-R-10)* was used as a self-report measure for child participants to screen for symptoms of depression during the past week. Suicidality in children was assessed using the 2-item self-report *Ask Suicide-Screening Questions (ASQ)* [51]. The study staff member administered the Columbia-Suicide Severity Rating Scale (C-SSRS) [52] when there was elevated risk and followed the study-approved risk management procedures; imminent risk was treated as a psychiatric emergency.

Quality of life. The *Pediatric Quality of Life (PedsQL)* [53] is a 23-item self-report questionnaire that was used to assess physical, emotional, social, and school functioning in the past month.

Teasing. History of experiences with weight-based teasing was measured using an adapted version of the *Adolescent Experiences with Weight and Bullying* self-report questionnaire [54]. This questionnaire assessed type of bullying experienced (if any) and consequences experienced due to weight-based teasing. To measure the child's ability to cope with teasing and to monitor teasing throughout the study, the 6-item problem-focused Adapted Coping with Teasing subscale of the *Coping with Teasing Scale* [55] was used.

1.12. Parent/caregiver report

Parent/Caregiver Depression and Anxiety Screening. Parents/caregivers completed the 9-item self-report *Patient Health Questionnaire (PHQ-9)* [56] to assess symptoms of depression and suicidality. Parents at elevated risk were administered the C-SSRS (for safety purposes, not an outcome); if elevated or imminent risk was confirmed, the staff member followed the study risk management procedures. Parents/caregivers also completed the *General Anxiety Disorder-7 (GAD-7)* self-report questionnaire to screen for symptoms of general anxiety.

Quality of Life. Parents/caregivers completed the *12-Item Short form Survey (SF-12)* [57], an abbreviated version of the 36-item questionnaire, used to measure functional emotional and physical health and well-being over the last 4 weeks.

Motivation. To examine their motivation to begin or continue eating a healthy diet and regularly engage in physical activity, parents/caregivers completed the 8-item Autonomous Self-Regulation subscale of the *Treatment and Self-Regulation Questionnaire* [58].

Perceived support. Parents/caregivers completed the *Health Care Climate Questionnaire (HCCQ)* [59], a 15-item questionnaire used to measure perceived supportiveness from healthcare providers regarding health behavior change. Follow-up assessments at month 1.5 (sent by email) and then months 6, 12, and 18 asked about PCP (for all families) and FBT coaches (for those in the eSOC+FBT condition).

Household Chaos. To measure environmental disorder in the home, parents/caregivers completed the 15-item *Confusion, Hubbub, and Order Scale* [60].

Family Nutrition and Physical Activity. Parents/caregivers completed the 20-item *Family Nutrition & Physical Activity Screening Tool (FNPA)* [61] used to measure family environments and practices related to family meals, family eating practices, food choices, beverage choices, restriction/reward, screen time, healthy environment, family activity, child activity, and family schedule/sleep routine.

Demographics. Demographics were assessed for descriptive and covariate analysis purposes. Parents/caregivers self-reported household income, and parent/child education level, medication use, sex, gender, and race/ethnicity. A validated 2-item measure [62] was used to assess for food insecurity, and income volatility and predictability were measured with a 3-item questionnaire [63,64].

Changes in Health History. Parents/caregivers were interviewed to report potential adverse events and what, if any, weight-related medical visits the child attended outside of the primary care setting, with whom, for what duration, and the purpose of the visit(s). Adolescents (≥13 years) were also asked to report their own changes in health history.

1.13. Parent-report on child

Child Psychosocial Functioning. Parents/caregivers completed the *Pediatric Symptom Checklist-17 (PSC-17)* [65], an abbreviated version of the original 35-item scale to capture emotional and behavioral symptoms.

Impact of Weight on Child Functioning. The *Sizing Them Up* [66] questionnaire is a 22-item parent/caregiver report tool that was used to assess the impact of weight on the child's health and daily functioning over the last month.

1.14. Provider measures

Provider Survey. Each PCP and FBT coach provided consent and then completed the *Provider Survey* at the beginning and end of their participation in the trial. This survey was adapted from the POWER [67] and PROPEL [68] weight loss trials and assessed demographics, clinical care, research activities, and knowledge about weight management practices. This survey utilized the provider acceptance subscale of the *Evidence-Based Practice Attitude Scale* [69], the weight bias subscale of the 14-item *Fat Phobia Scale* [70], provider competence [71], and provider intended uptake as measured by an adapted item from Scott [72].

1.15. Other study measures

Parallel Medical Record Data. A parallel effort of clinical and laboratory measurement collection was done utilizing EMR and/or paper medical charts at the participating clinics. A retrospective chart review covering the period of intervention and up to 2 years prior and 11.5 years after was conducted to assess changes in variables of interest. These EMR data are also used to supplement study-measured height and weight data in the case of a missed assessment visit.

Adverse Events. At each assessment time point, parent/caregiver and child participants reported any unexpected health events that occurred during the duration of the study. The relatedness of the event to the study, expectedness, severity, and frequency of the event was reported to the DCC, and in the case of a serious adverse event was reviewed by the study medical investigators and reported to governing bodies as required.

eSOC Fidelity. Medical record data were used to measure fidelity and treatment dose of eSOC, including frequency of follow-up visits scheduled and attended within the clinics and follow-up for specialist referrals and labs ordered. Recorded audits and practice-level changes in provider billing for obesity services were also assessed when available.

FBT Fidelity. The Dashboard, mentioned above, was completed by FBT coaches for each session and used to measure the fidelity of FBT. Session audio recordings were randomly audited and rated by study supervisors.

1.16. Analytic plan

All analyses adhere to the Methodology standards of the study's main sponsor, the Patient-Centered Outcomes Research Institute (PCORI)

[73]. Means and frequencies are tabulated to describe the participants, providers, and clinical practices, and to confirm no baseline differences by treatment arm among the participants. The primary analytic strategy for assessing intervention effects is a mixed model repeated-measures analysis of variance overall and within race and sex subgroups, using child percent overweight at each timepoint. To examine if the intervention impacts children and adolescents differently based on age, the variable age is tested as a moderator on the primary outcome using the Baron and Kenny method [74] and bootstrapping methods [75]. Primary and secondary endpoints are analyzed as continuous variables. In all analyses, we adjust for confounders including the practice site and provider using random effects and evaluated group-by-site interactions to determine whether the effectiveness of the intervention differs by site. Additional covariates include enrollment related to before or during the COVID-19 pandemic and number of trainings attended by PCPs, among others. Data are analyzed with SAS using the intent-to-treat principle.

2. Conclusion

TEAM UP is one of the largest pragmatic trials of an intensive health behavior lifestyle treatment program delivered for children and adolescents with obesity within primary care. Importantly, families and other partners informed the study design, recruitment materials, and measures, and provided ongoing input throughout each phase of study implementation. For pragmatism, the IHBLT program was imbedded within the primary care practice in conjunction with PCP-led counseling as recommended by the AMA and the AAP. All study decision making was based on trying to mimic, as closely as possible, what would happen in non-research clinical practice. Trial results inform the effectiveness of integrating IHBLT with the provider-led (eSOC) approach for changing children's and parents' relative weight outcomes as well as influence other patient-centered outcomes including psychosocial variables and relevant comorbid conditions. Broad eligibility criteria, a focus on clinical practices with a large proportion of Medicaid members, and a concerted effort to enroll racial and ethnic minority populations contribute to the potential generalizability of findings. Heterogeneity of treatment effects are examined to identify potential difference in effectiveness among sub-groups including between boys and girls and between White and non-White participants. The RE-AIM analysis provides in-depth examination of uptake, acceptability, and implementation, as well as likelihood of sustainability. TEAM UP provides timely, important results to inform the delivery of care and treatment options for children and adolescents with obesity.

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Declaration of competing interest

The authors have no competing interests to disclose.

Data availability

Data will be made available on request.

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Appendix

Training of TEAM UP Primary Care Providers to Deliver enhanced Standard of Care.

eSOC Training Stage	Pre-Work	Core Curriculum *Phase 1*	Fidelity & Sustainability *Phase 2*	Ongoing Engagement & Sustainability *Phases 3, 4 & 5*
Dates	February–April 2019 Or when the PCP joined the study	April–July 2019 Or when the PCP joined the study	September 2019–August 2020	September 2020–February 2023
Format	Self-paced modules and one-on-one introductions to faculty & staff	Utilized ECHO Methodology Monthly Virtual* Sessions with Case presentations	Continued virtual* ECHO Quality improvement project: Multiple data cycles, PDSAs, Team reporting	Virtual* learning collaboration Key topics & occasional case discussion Ongoing technical assistance Faculty and/or staff provided relevant case examples, where appropriate
Duration	Self-paced modules	60 min	60 min	60 min
Key Topics Covered	Team Up Introductions Motivational Interviewing Welcome Call with Faculty & AAP Staff Pre-Project Survey ChangeTalk MI Simulations	Introduction and Orientation to eSOC Pathophysiology Assessment & Management Practice Workflow, Coding & Billing The Provider Approach Weight Bias & Stigma Cultural Considerations Behavioral Counseling	Follow Up Visits Developmental Approach Addressing Patient & Family Setbacks Talking with Patients and Families Obesity Care During the Pandemic Frontline Utilization Sustaining Your Practice Changes	Obesity: A Complex Chronic Disease Goal Setting Using Rewards Obesity & COVID Enrolling Families in eSOC Self-Monitoring Opening the Conversation Obesity Coding & Billing Depression and Anxiety in Children w/Obesity Patient Engagement and Retention Identifying & Managing Pre-Diabetes Maintaining Treatment in Primary Care Multi-Disciplinary Treatment in Primary Care Role of Anti-Obesity Medications in Treatment

* Virtual session participation could be live (videoconferencing) or via recordings; live participation encouraged.

Training of TEAM UP Family-based Behavioral Treatment (FBT) Coaches to Deliver FBT.

FBT Training Stage	Pre-Work	Core ECHOs Required for training/FBT Certification	Sustainability ECHOs Optional	Supervision
Dates	June–November 2019 Or when the coach joined the study	September–November 2019	November2019-February 2020 Booster training ECHO in February 2021	September 2019-Currently ongoing
Format	13-h in-person training with live and recorded presentations Virtual training with pre recorded presentation on material FBT role play sessions	Utilized ECHO Methodology Virtual* Sessions with Case presentations	Utilized ECHO Methodology Monthly	Virtual* learning collaboration 2×/month (reduced to 1×/month during final 6 months) Key topics & occasional case

(*continued on next page*)

(*continued*)

FBT Training Stage	Pre-Work	Core ECHOs Required for training/FBT Certification	Sustainability ECHOs Optional	Supervision
	Self-paced material review- review of lesson plans, handouts Book review- *The Everyday Parenting Toolkit* (Kazdin & Rotella, 2014), *Childhood Obesity (Advances in Psychotherapy-Evidence-Based Practice*; Wilfley, Best, Holland, & Van Buren, 2018) EMR/Data entry training Final Simulation review completed by trained staff	Weekly meetings for 1 month, bi weekly for 2 months		discussion, but did not follow ECHO format Ongoing technical assistance Faculty and/or staff provided relevant case examples, where appropriate
Duration	Self-paced modules	60 min	60 min	60 min
Key Topics Covered	Family-Based Treatment Key Topics- Healthy Eating Physical Activity Routines Social Facilitation Maintenance & Relapse Prevention Nature and Treatment of Childhood Obesity Parenting Strategies	"Dashboard" FBT EMR system Shaping Goals Self-Monitoring Rewards System Meal Planning Parenting Behaviors Teasing and Bullying Care Coordination	Working with Families of Low Socio-economic Status Body Image Food Fussiness Patient Retention REDCap FBT Dashboard Cultural Adaptations Implicit Bias Social Influences Success post-TEAM UP	Relevant program updates EMR / Data entry queries and questions Specific family issues and barriers Common topics that were discussed within individual supervision. Specific questions and cases coaches brought to the meeting

* Virtual session participation could be live (videoconferencing) or review didactic only via recordings; live participation encouraged.

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