STUDY PROTOCOL

Social Behavioral Template

Implementation of Decision Support for the Management of Obesity in a National Pediatric Primary Care Research Network

Protocol Number

2000033551

Protocol Version

1/16/2026

1.11

Clinical Trials Registration Number: NCT05627011

Synopsis

Purpose

This study, *Improving Pediatric Obesity Practice Using Prompts* (iPOP-UP), will evaluate a newly-optimized intervention, including electronic health record (EHR)-based clinical decision support tools (CDS) to improve adherence to national guidelines for management of childhood obesity, among 81 primary care practices, grouped into 71 clusters, affiliated with three health systems serving children with racial and ethnic, socio-economic, rural-urban, and geographic diversity.

Objectives

Primary Objective: To evaluate the effectiveness of the iPOP-UP implementation package in improving clinical care and child BMI in pediatric primary care settings

Secondary Objective: To assess the impact of the implementation strategy on the reach, adoption, fidelity, cost, and maintenance of the intervention

Study Population

The unit of randomization in this study is pediatric primary care practice.

Clinician-participants: Within the participating 71 clusters of 81 practices, pediatric primary care clinicians working at the implementation sites will be invited to participate in post-intervention surveys and interviews assessing their knowledge, attitudes, and practice. In addition, limited data (to include dates and geographic information but no facial identifiers) will be queried and analyzed for the above-described pediatric primary care clinicians,

Patient-participants: Limited data (to include dates and geographic information but no facial identifiers) will be queried and analyzed for all children 1) age 2.0 to ≤18 years-old at baseline, 2) with a well-child visit, during which height and weight are measured, at one of the participating practices during the study period, and 3) with a BMI ≥85th percentile for age/sex (CDC criteria for overweight/obesity).

Parent/caregiver-participants: Parents/caregivers of patient-participants seen for a well-child care visit at an intervention site will be invited to participate in an interview exploring their perceptions of the care delivered during their child's recent visit, including how they felt about conversations about weight, growth, healthy behaviors and any bias/stigma they perceived during these clinical encounters.

Number of Participants

Number of practices: 81, grouped into 71 clusters

Number of primary care clinicians at these practices at baseline: ~800

Estimated number of pediatric patients at these practices at baseline: ~188,800

Number of parents/caregivers to be interviewed: approximately 60 (sample will depend on thematic saturation)

Study Design

This multi-site, parallel 2-arm cluster randomized controlled “Hybrid Type 2” effectiveness-implementation trial will use mixed methods (EHR data analysis, surveys, and interviews/focus groups) to allow the study team to simultaneously evaluate (1) the effectiveness of the iPOP-UP implementation package in improving clinical care and children’s BMI outcomes in pediatric primary care setting and (2) the impact of the implementation strategy on the reach, adoption, fidelity, cost, and maintenance of the intervention.

Study Duration

The entire study, including data analysis, will last about three years.

Patient and clinician participation will be up to 24 months.

Parent/caregiver participation will be limited to one interview.

Outcome Variables

- One-year change in BMI, measured as a percentage of the 95th percentile for age and sex
- Change in clinicians’ objective practice around managing elevated BMI in primary care using EHR data
- Change in clinicians’ self-reported knowledge, attitudes, and practice around managing elevated BMI in primary care
- Utilization of CDS tools
- Cost of implementation

Locations/Facilities

We will randomize 71 clusters representing 81 practices that have agreed to participate in the study from the three participating health systems, which represent rich heterogeneity in practice type, geographic region, rural-urban distribution, race/ethnicity, and insurance type (a marker of SES) of the patients they serve. The study will not involve practices outside of the United States.

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Abbreviations

Abbreviation	Explanation
AVS	After-visit summary
CDS	clinical decision support
EHR	electronic health record

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Glossary of Terms

Glossary	Explanation
iPOP-UP	*Improving Pediatric Obesity Practice Using Prompts*, the intervention being tested

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Protocol Revision History

Version Date	Summary of Substantial Changes
Version 1.0 10/27/2022	--
Version 1.01 02/02/2023	Updated to reflect final number of practices (and associated clinicians and patients) that agreed to participate in trial, and add NCT#.
Version 1.02 8/21/2023	Updated to reflect that qualitative components of the study summative evaluation will begin at six months, and not occur at 12 and 18 months, and to clarify expected duration of summative evaluation mixed methods efforts.
Version 1.03 9/13/2023	Updated to add in-person survey recruitment and clinic-level incentives.
Version 1.04 11/2/2023	Updated to reflect additional logistics around in-person survey recruitment
Version 1.05 3/7/2024	Updated to address contradictions in earlier versions of the protocol regarding email addresses queried from the EHR and study participant contact information. Revisions can be found on page 32.
Version 1.06 5/28/2024	Updated with change to incentive amount for qualitative summative evaluation participants
Version 1.07 7/11/2024	Updated to add snowball sampling as recruitment method for qualitative summative evaluation
Version 1.08 12/02/2024	Updated to add qualitative exploration of families' experiences with care
Version 1.09 2/18/2025	Updated to add additional detail around site-specific practices for recruitment.
Version 1.10 5.30.2025	Updated to add IU Health as part of one of our study sites for recruitment purposes
Version 1.11	Updated errors/outdated details present in the protocol (e.g., number of practices, inclusion criteria for patient data query etc.)

1.16.2025	

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1. Background

1. Background

CDS tools are seen as a key piece of the potential inherent in EHRs to improve the quality of healthcare overall[1], and could benefit the quality of pediatric obesity management given studies finding low rates of documentation and treatment[2-4]. In terms of CDS tools specific for pediatric obesity, the evidence is mixed: while some studies have demonstrated that EHR-based CDS tools can be effective in increasing adherence to clinical recommendations in pediatric obesity[5-9], not all CDS implementations have impacted care as desired[10, 11]. The studies with positive results, however, were mostly implemented in limited settings, so it may be difficult to replicate their results on a wider scale. As such, this study is designed to test, on a larger scale, an optimized version of a previously studied CDS tool that yielded positive results[8]. Based on this tool's effectiveness, it has been further refined and optimized into the iPOP-UP intervention based on a formative evaluation conducted with clinicians and other stakeholders at three health systems representing more than 80 heterogeneous clinics. This trial has the potential to advance the effectiveness and implementability of CDS tools for pediatric obesity, the need for which has never been greater given the increase in already-alarming prevalence of and inequities within this epidemic nationwide.

2. Prior Experience (if applicable)

The EHR-based CDS tools included in the iPOP-UP intervention were originally tested, and found to be effective, in a small-scale pilot study at one health system.[8] Prior to the study described in this protocol, the study team led a formative evaluation, the results of which informed the optimization of the CDS tools being studied.

2. Rationale/Significance

1. Rationale and Study Significance

Nearly 1 in 3 children and adolescents in the United States are affected by overweight or obesity, and low-income, non-Hispanic Black, Hispanic/Latino and rural children are disproportionately impacted.[12] Despite guidance from the US Preventive Services Task Force and expert committees, pediatric primary care clinicians often do not follow available guidance for managing children with obesity.[13] EHRs have the potential to improve clinicians' diagnosis and management of obesity by providing tools such as reminders and clinical decision support. We have demonstrated that the *Improving Pediatric Obesity Practice Using Prompts* (iPOP-UP) intervention package, consisting of EHR-based CDS tools for pediatricians and educational materials for parents, improved BMI among children in two clinical trials at a multisite group practice in Massachusetts.[8] However, little is known regarding the effectiveness of the iPOP-UP intervention in various pediatric primary care settings, particularly those serving children from populations disproportionately impacted by obesity, or regarding the specific factors that influence the successful adoption and implementation of

these tools. In partnership with a national practice-based research network, we aim to capitalize on advances in the field of Implementation Science to apply and evaluate iPOP-UP for childhood obesity among 81 primary care practices grouped into 71 clusters affiliated with three health systems serving children with racial/ethnic, socio-economic, rural-urban, and geographic diversity. We hypothesize that the CDS tools included in the iPOP-UP intervention will improve primary care clinicians' management of pediatric obesity by increasing adherence to evidence-based clinical recommendations. The clinical outcome of interest is one-year change in BMI for children who receive primary care at the enrolled clinics.

The iPOP-UP intervention will include a set of CDS tools as well as training documentation and patient-facing materials to promote clinician adherence to upcoming guidelines from the American Academy of Pediatrics (AAP) for the management of childhood overweight and obesity (scheduled for publication December 2022), as described in the below table.

Table 1. Intervention Components

EHR-based Clinical Decision Support Tools	In-line BestPractice® advisory with notice of BMI≥95th %tile and links to: - SmartSets® - Note template - Evidence-based childhood overweight and obesity guidelines; SmartSet® and well-child obesity note template facilitate: - Documentation/coding of obesity-related diagnoses; - Orders for obesity-related screening laboratory tests, medications and referrals to weight management programs, nutrition, subspecialists for eligible patients; - Counseling using motivational interviewing and goal setting per the AAP guidelines with educational materials on healthy behaviors for the after-visit summary provided to families and links to resources available through the AAP - Health maintenance tools that can remind families, via the patient portal and/or AVS, of ordered and/or overdue labs, upcoming visits, etc.
Provider Training	To include a variety of modalities, including tip sheets on the new EHR tools, video recorded demonstrations of the tools, and presentations during clinical meetings. Clinicians will also be encouraged to use training materials available to all clinicians from the AAP.

2. Risks

We anticipate minimal risk associated with study data collection. For the purposes of recruitment, providing incentives to participants, and tracking changes in participants' pre-post survey responses, we will track identifiable information of invitees, including names and email addresses. These will be kept separate from all transcripts and analyses. All paper-based survey data will be scanned and securely transferred to Yale staff, who will then enter it into REDCap; scanned surveys will include the study-specific de-identified ID to facilitate REDCap entry. All survey data will be kept in the secure, password-protected REDCap system and/or in password-protected files on Yale-managed servers. All qualitative data from interviews/focus groups will be kept on secure, institution-managed servers with recordings stored on Yale and/or UFL servers, and transcripts stored on Yale servers. Existing patient-and clinician-level data will be collected by EHR data warehouse staff at sites, who will remove all facial identifiers (e.g., names, street addresses, telephone numbers, email addresses, social security numbers, medical record numbers, facial photos,

etc.) prior to transfer to the Yale Data Coordinating Center. Because this data will be collected at sites but analyzed at Yale, we will use encrypted secure file transfer procedures to transfer the limited datasets. We will keep electronic data on a restricted server that is on a password protected network at all times. None of this data will be individually identifiable by study investigators.

As we will not analyze identifiable information, we anticipate minimal risks associated with the intervention and trial. For clinicians, there is a risk that the decision support and other tools could have unexpected adverse consequences such as creation of more work, unfavorable workflow issues, and overdependence on the technology. Although important to consider (and we will explore these themes in our mixed methods evaluation), these issues are balanced by the evidence suggesting the effectiveness of computerized CDS tools to improve the quality of patient care. In addition, it is essential to point out that the iPOP-UP intervention is an enhancement of the existing electronic health record, not the implementation of a whole new system of care; therefore, the risks to clinicians and patients are expected to be negligible. Specifically, for clinicians, the intervention has the risk of slowing down the operating speed of the EHR or disrupting the workflow of clinicians who view the alerts.

For the patients, the risks are those that are typically undertaken in the receipt of general medical care. That is, it is conceivable that the intervention could result in a change in management (e.g., decision to obtain a screening laboratory test or refer to a weight management program), which may lead to a side-effect, but in fact is more likely to lead to a clinical benefit. There also is the possibility of psychological risk to patients associated with being labeled as having an elevated BMI; however, this risk is outweighed by the potential benefits associated with better identification, evaluation, and treatment of obesity by their clinicians and we will engage patients/parents in the user-centered design to avoid this.

For the parent/caregiver participants, there is a risk that the interview questions we ask could be emotionally laden, given the stigma and bias associated with overweight/obesity. None of the interview questions will be required, and participants will be able to end the interview at any time without consequence.

Another important risk we have considered is the risk created by the randomized controlled trial design of the proposed study. The withholding of effective EHR tools from practices and clinicians in one study arm versus the other. However, there remains equipoise regarding the benefit EHR-based CDS tools in different practice settings and patient populations, both in general and specifically for treatment of obesity. Therefore, a cluster randomized controlled trial is justifiable and necessary to assess the true benefit of the intervention.

3. Anticipated Benefits

This dissemination and implementation study is based on a prior cluster randomized controlled trial in pediatric primary care practices in Massachusetts which demonstrated improved BMI using EHR-based CDS tools to support the adoption of prior expert recommendations for the management of obesity in primary care. We expect that practices and clinicians in the intervention arm of the trial will be supported in their workflows to provide more efficient and high quality care and that children seen in these practices during

the trial will see both short- and long-term benefits from improved treatment of obesity that could reduce their weight gain and help with the management of other chronic conditions.

This research has the potential benefit of improving the diagnosis and treatment of obesity among patients at the practice sites which ultimately could reduce their weight gain and help with the management of other chronic conditions. Patients at other pediatric primary care sites may ultimately benefit as well through the dissemination of our results and the iPOP-UP intervention itself.

Long-term potential benefits to society as a whole include lower health-care costs, given the many complex and costly physical and mental health sequelae tied to pediatric overweight/obesity. Interviews with parents/caregivers are expected to yield important insights into how primary care clinicians can manage overweight/obesity in pediatric populations while minimizing any unintended harm via stigmatizing care.

3. Study Purpose and Objectives

1. Purpose

This study will evaluate iPOP-UP, a newly-optimized intervention to improve adherence to national guidelines for the management of childhood obesity, among 71 clusters of 81 primary care practices affiliated with three health systems serving children with racial and ethnic, socio-economic, rural-urban, and geographic diversity.

2. Hypothesis

We hypothesize that in practices randomized to receive the iPOP-UP intervention, primary care clinicians' management of pediatric obesity and adherence to evidence-based clinical recommendations will increase, and that children with obesity who receive primary care at intervention sites will have more of an improvement in one-year change in BMI compared to children at control sites. Specific key questions that the study is expected to answer include:

1. To what extent will 2-18 year-old children with elevated BMI seen during the intervention period be more likely to have problem list/visit diagnoses indicating high BMI, orders for recommended obesity-related laboratory tests, medications, follow-up visits, and referrals among the intervention vs. usual care practices?
2. To what extent will patients with elevated BMI seen in the intervention versus control practices have a slower one-year increase in BMI?
3. To what extent will baseline practice and patient-level factors such as practice type, urban-rural location, and size and patient's race/ethnicity, insurance status, the severity of overweight/obesity and neighborhood characteristics be associated with the impact of the intervention and implementation strategy?

3. Objectives

Primary Objective: To evaluate the effectiveness of the iPOP-UP implementation package in improving clinical care and child BMI outcomes in pediatric primary care settings affiliated with three health systems serving children with racial and ethnic, socio-economic, rural-urban, and geographic diversity

Secondary Objective: To assess the impact of the implementation strategy on the reach, adoption, fidelity, cost, and maintenance of the intervention

4. Study Design

Trial design: a large-scale, multi-site, parallel 2-arm cluster randomized controlled trial "Hybrid Type 2" effectiveness-implementation study to simultaneously evaluate (1) the effectiveness of iPOP-UP in improving clinical care and child weight outcomes in pediatric primary care setting and (2) the impact of the implementation strategy on the reach, adoption, fidelity, cost, and maintenance of the intervention.

Method for assigning participants to study groups: covariate-constrained randomization[14]

- Clusters will be randomized 1:1 using a covariate constrained randomization to help maintain balance across treatment arms on key practice characteristics. We will consider the following characteristics of practices and evaluate correlations to identify a parsimonious set of key characteristics: health system, proportion of patients that are publicly insured, proportions non-Hispanic Black, proportions Hispanic/Latino, proportions non-Hispanic White, geographic location (rural versus urban/suburban), practice size/volume, and academic vs. non-academic. Since randomization will be at the practice level, but the analysis will be conducted at the individual level, we will assess the adequacy of the randomization by comparing baseline demographic and clinical characteristics between the two treatment groups.
- Randomization method: covariate constrained randomization
- Unit of randomization: practice cluster
- Role responsible for generating and implementing the randomization schema: study statistician
- How randomization errors will be handled: We will employ a SAS macro for covariate constrained randomization and use a random seed to generate the randomization. All sites will be identified at the same time as to which treatment arm they have been assigned. We will handle any unforeseen errors in randomization by maintaining our intent-to-treat analysis approach and may conduct sensitivity analyses to evaluate protocol deviations.[15]

Number of study groups: two (one intervention, one control)

Name and brief description of study intervention: The study intervention, iPOP-UP, involves EHR-based CDS tools refined through a formative evaluation and user-centered design process that immediately preceded this study.

Control group: practices assigned to usual care that will not have access to the iPOP-UP CDS tool but will have access to many opportunities available to all pediatric clinicians nationally around the release of the new American Academy of Pediatrics guidelines for obesity management. We have timed the launch of our study to coincide with the launch of these guidelines.

Stratifications planned: We will assess the extent to which baseline practice and patient-level factors (such as practice type, urban-rural location, and size and patient's race and ethnicity, insurance status, the severity of overweight/obesity, and neighborhood

characteristics) are associated with the impact of the intervention and implementation strategy.

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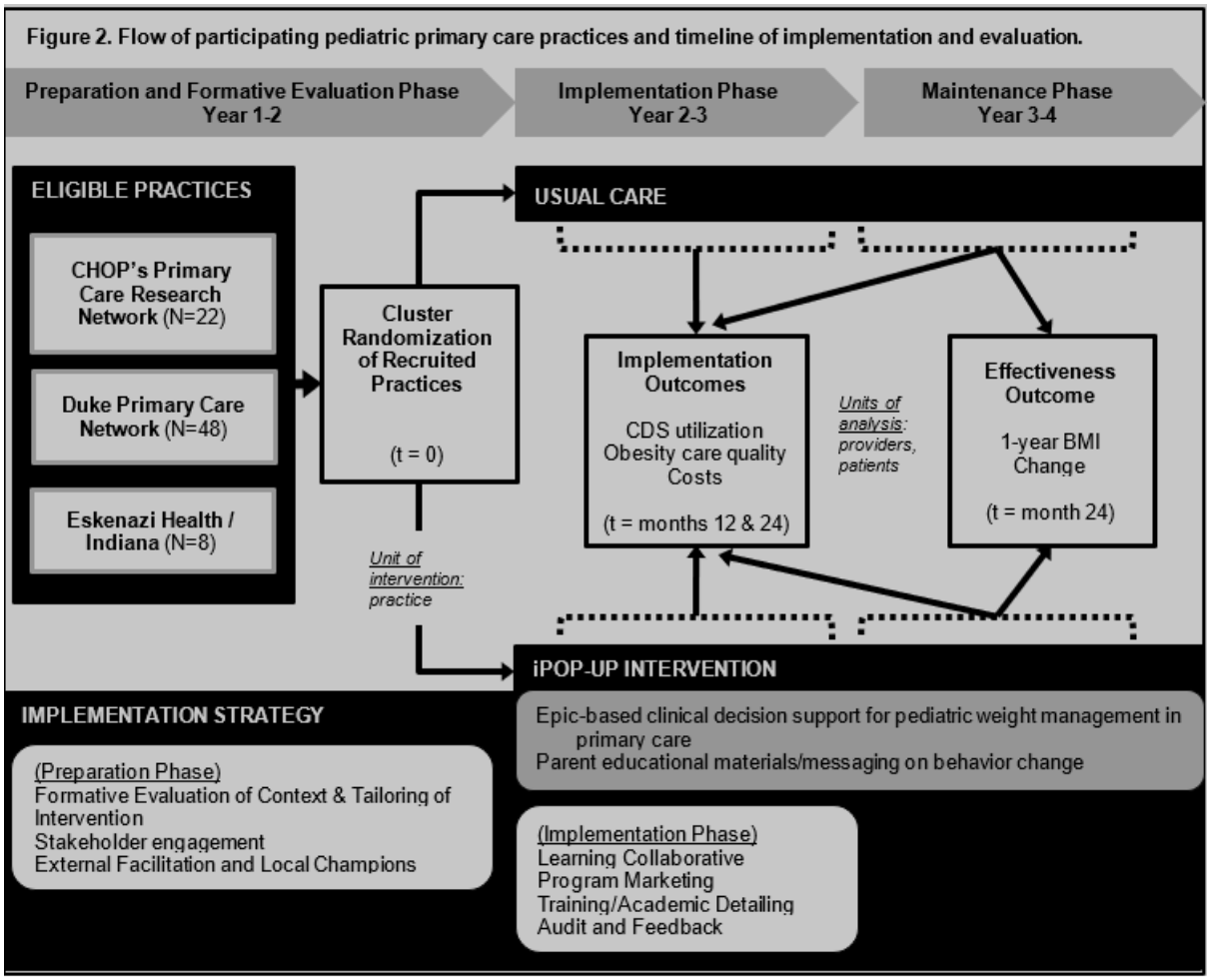
Study flowchart:



1. Study Duration

The entire study, including data analysis, will last about three years. Patient and clinician participation will be up to 24 months.

2. Outcome Variables/Endpoints

1. Primary Outcome Variables/Endpoints

OBJECTIVES	ENDPOINTS	RATIONALE FOR ENDPOINTS
To evaluate the effectiveness of our intervention package in improving clinical care and child weight outcomes in pediatric primary care setting caring for low-SES and racial/ethnic minority children	1.1: Change in BMI, measured as a percentage of the 95th percentile for age and sex, over one year 1.2: Composite measure of adherence to clinical guidelines at 6 months post-intervention, for visits completed among children 2-18 years-old with BMI ≥85th percentile. Adherence defined as evidence of recommended obesity-related care during the study period including all of the following: 1. Inclusion of diagnosis code indicating high BMI in problem list (cumulative) or visit diagnosis (every visit) 2. Recommended screening lab orders for obesity related comorbidities, if eligible	We hypothesize that: 1.1: patients with elevated BMI seen in the intervention vs. control practices will have a slower one-year increase in BMI measures 1.2: Clinicians in intervention vs. control practices will be more likely to adhere to clinical guidelines during visits for patients with elevated BMI.

OBJECTIVES	ENDPOINTS	RATIONALE FOR ENDPOINTS
	3. Appropriate BP screening in children 3 and older 4. Counseling diagnosis codes or structured documentation (every visit) 5. Follow-up visit requested (every visit) or referral (need to look back) for further management of obesity	

2. Secondary and Exploratory Outcome Variables/Endpoints

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
To assess the impact of the implementation strategy on the reach, adoption, fidelity, cost, and maintenance of the intervention	2.1: Composite measure of adherence to clinical guidelines at 12 and 18 months post-intervention, for visits completed among children 2-18 years-old with BMI ≥85th percentile. 2.2. Visits completed among children with BMI ≥85th percentile with evidence of recommended obesity-related care during the study period: 1. Inclusion of diagnosis code indicating high BMI in problem list (cumulative) or visit	We hypothesize that: 2.1: Clinicians in intervention vs. control practices will be more likely to maintain adherence to clinical guidelines. 2.2: Clinicians in intervention vs. control practices will be more likely to adhere to the components of clinical guidelines. 2.3. Clinicians in intervention vs. control practices will be less likely to order lab tests that are not routinely recommended. 2.4. Clinicians in intervention vs. control practices will be more likely to be more likely to

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	diagnosis (every visit) 2. Screening lab orders for obesity related comorbidities, if eligible 3. Appropriate BP screening in children 3 and older 4. Counseling diagnosis codes or structured documentation (every visit) 5. Follow-up visit requested (every visit) 6. Referral (need to look back) for further management of obesity 7. Weight loss medication orders, if eligible 8. Bariatric surgery program referrals, if eligible 2.3: Visits completed among children with BMI ≥85th percentile with lab orders for laboratory tests not routinely recommended including insulin test and thyroid function tests 2.4. Change in clinicians' knowledge attitudes and	improve their self-reported knowledge, attitudes, and practice. 2.5: We aim to describe CDS utilization post-intervention. 2.5. We will estimate costs of implementation and delivery of the iPOP-UP intervention compared with usual care. If effective, we will also estimate the cost-effectiveness of the iPOP-UP intervention compared with usual care.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	practice around elevated BMI in primary care 2.5: EHR measures of CDS utilization 2.6: Cost and cost-effectiveness of implementation	

3. Study Population

Clinician-participants: clinicians (including physicians-in-training (residents and fellows), physicians, nurse practitioners (NP), and advanced practice registered nurses (APRNs)) who work at study sites during the intervention.

Patient-participants: all eligible patients who receive well-child care at the study sites via a limited data set which will exclude all “facial” identifiers.

Parent/caregiver-participants: Parents/caregivers of patient-participants seen for a well-child care visit at an intervention site within about two weeks to one month of data collection

4. Number of Participants

	CHOP	Duke	IU	Total
Practices	21	47	13	81
Practice clusters	19	44	8	71
Clinician-participants	~230	~400	~170	~800
Patient-participants	~ 89,600	~ 71,360	~ 29,600	~188,800
Parent/caregiver-participants	~15-25	~15-25	~10-20	~60

5. Eligibility Criteria

Inclusion criteria:

Primary Care Practices: all primary care practices using the EHR system of one of the 3 health systems participating in the study that agree to participate in the iPOP-UP trial (see recruitment information below)

Clinician-participants: all clinicians who delivery pediatric primary care at the participating practices, including physicians and physicians-in-training (residents and fellows), nurse practitioners (NP), and advanced practice registered nurses (APRNs)

Patient-participants: all patients ages 2-18 with overweight/obesity seen during the study period may be impacted by the intervention. A limited dataset will be collected for the subset of these patients with at least one visit at any point during the study period (Feb 2021 – December 14, 2024) with the following criteria:

- Visit conducted by a **prescribing clinician** (physician (MD/DO, including residents and fellows), NP, PA)
- **Any completed visit type** in a **primary care department** participating in iPOP-UP (control and intervention)
- **height and weight measurement present**
- **patient age of 2 to 18 years old**, inclusive
- **BMI ≥ 85th percentile for age and sex**

Parent/caregiver-participants: English- or Spanish-speaking parents/caregivers of patient-participants seen for a well-child care visit at an intervention site within one month of data collection who meet the following inclusion criteria:

1. Parents/caregivers of children age between 2-18 years inclusive
2. Child with BMI at or above 85th percentile
3. Parents/caregivers who confirm that their child's weight or growth was discussed in their most recent pediatric clinic visit
4. Date of last pediatric clinic well visit within last month
5. Able to communicate verbally in English or Spanish
6. Has phone or internet access necessary to complete an interview by video chat or phone
7. Has opted in/did not opt out to being contacted for participation in pediatric healthcare research

Exclusion Criteria:

Clinician & patient-participants: None – exclusion criteria are purposefully limited in this real-world implementation study

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Parent/caregiver-participants: Parents/caregivers who do not meet our inclusion criteria.

6. Recruitment Procedures

Practice-level recruitment: The study teams at each participating health system decided upon the best recruitment approach given local policies and preferences. Two contacted all pediatric primary care practices affiliated with their health systems to invite them to participate in the study. This contact was personalized, with teams contacting each practice's leadership individually to invite their participation and answer all questions. Contact methods included phone, Zoom, or in-person discussion. The site teams have pre-existing relationships with many of these practices, and as such, personalized their recruitment to the greatest extent possible. The third presented the study to system leadership to get buy-in and approval for the affiliated sites to participate.

Individual-level recruitment:

Clinician-participants: The only individual-level recruitment of clinicians in this study will be for the post-intervention study surveys and post-intervention interviews/focus groups. Study staff, including site investigators and Yale research team members, will invite all clinicians at all participating practices to participate in the study surveys; qualitative recruitment will be targeted to key informants and will be led collaboratively by Yale research team members and site study staff. All qualitative research will be conducted remotely on Zoom or another similar platform. Key informants may be defined by their level of use of the iPOP-UP intervention CDS tools (e.g., early adopters, late adopters, never adopters), by their engagement in the intervention overall (e.g., local Epic super users or other clinicians who provide trainings to colleagues, clinicians who participated in various training methodologies, etc.), or be identified via snowball sampling at the end of each interview. Recruitment will occur via email and/or in-person. Before site study staff visit a clinic participating in the trial to recruit for the survey in-person, Yale study staff will share the names and de-identified study IDs of clinicians who have yet to complete the survey so that site study staff do not recruit clinicians who have already completed the survey. Qualitative interviews/focus groups will most likely be led by Jessica Ray, study team member based at UFL, and may instead be facilitated by study team members at Yale or study sites who have unique and in-depth insight into the topic being explored (e.g., a Duke team member may lead a focus group with Duke Epic super users). Invitees will be offered a $10 or $75 electronic gift card, to be provided via email within ten business days of the completion of the survey or interview/focus group, respectively. In addition, for every clinician who completes a survey, we will provide that clinician's clinic with a $20-$50 credit, based on available funds, toward their team's choice of a patient- or staff-facing prize (including Reach Out and Read books, stickers, and/or obesity-related clinical management guides).

Parent/caregiver-participants: Recruitment and data collection is expected to commence late 2024 to early 2025. Each site will query patients to be contacted for recruitment based off the eligibility criteria and date of last well-visit. Details of eligible patients which will be queried, all accessed/obtained from the electronic medical record of the pediatric patients, will include:

- Phone number
- Child name and date of birth
- Age
- Sex
- BMI classification
- Race and ethnic background
- Primary language
- Insurance status
- Family residence census track
- Primary care practice in which the visit occurred

Sites will use internal processes to manage their recruitment lists and tracking. For instance, the Duke site will use MaestroCare/Epic (including pre-consent statuses) and/or RedCap to internally track eligible participants and approaches/recruitment of participants prior to consenting them.

Using this list, staff at each study site will contact the parents/caregivers of eligible patients via: (i) phone or (ii) in-person. After consent is obtained, eligibility will be further assessed, and basic information will be recorded using a REDCap questionnaire. Additional demographic information and contact information for scheduling will also be captured/confirmed prior to scheduling the interview. Study site partners may also perform chart reviews of EHR data of interviewees for variables of interest such as care quality and stigmatizing care (e.g., did the primary care clinician counsel on nutrition and physical activity, did the visit note include stigmatizing language). The linking of EHR charts to interviewees would also allow for corroboration and further analysis of content that may be captured during the interview.

The REDCap tool is submitted with this protocol for IRB review/approval. Participant lists queried by partner study sites will be stored on HIPAA-compliant REDCap servers at their respective local institutions. The tool will be used either by study staff (if recruited by phone or in person) to:

1. Provide basic study information
2. Screen potential participants for study eligibility
3. Collect study participant demographic information to confirm the accuracy of their linked EHR data
4. Link to an online calendar of the interviewer's availability to schedule the interview at a time that works for the participant
5. Create a de-identified study ID which will be used to link transcripts with participant characteristics (e.g., will not connect names)

The one-on-one interviews will be led by Yale team members and, where needed, translators. A semi-structured interview guide with probing questions will be utilized to explore the experiences of parents and their children (by proxy) during well child visits in which growth, weight, or obesity are discussed, exploring perceptions of weight bias or stigma. The interview

guide will be piloted with parents/caregivers from patient and public involvement and engagement (PPIE) groups to ensure the content is appropriate and relevant. Interviews are expected to last 30-45 minutes and will be audio recorded for subsequent professional transcription. Upon completion of the interview, participants will also be offered a $50 electronic gift card. This will be provided via email (or by text, for those with no email address) within ten business days following the completion of the interview. Participants are responsible for paying state, federal, or other taxes for the payments they receive for being in this study. Taxes are not withheld from their payments.

Afterwards, no further involvement or follow-up with the participants will be undertaken.

7. Sampling Strategy

Parent/caregiver-participants: Sampling will involve both purposive and maximum variation approaches to ensure inclusion of heterogenous perspectives, with particular attention to the inclusion of participants from demographic backgrounds disproportionately affected by obesity and populations that may experience differences in care delivery. As such, participant factors which will be sampled for will include: race, ethnicity, primary language spoken (purposive sampling criteria) as well as children's age, sex, BMI category, insurance status, and clinic site and parent's health literacy.

8. Consent/Assent Procedures/HIPAA Authorization

We will only collect a limited data set, without "facial" identifiers, for patient-level EHR data or for clinician-level use of the iPOP-UP CDS tool and given the low risk to participants; as such, we plan to obtain a waiver of consent for participants involved in the main clinical trial.

For the survey, we will attach an information sheet to the emailed invitation to participate in the survey and will provide a copy of the information sheet when recruiting in-person. Consent will be implied by completing the survey itself; as such, we plan to obtain a waiver of consent for the survey.

For the interviews/focus groups with clinicians, we will attach an information sheet to the emailed invitation to participate. Verbal consent will be confirmed prior to beginning the interview.

Parent/caregiver interviews

For parent/caregiver interviews, a waiver of HIPAA authorization/consent is requested to access the patient information for screening and recruitment purposes, and to record information of interested caregivers prior to consent. For parent/caregivers who express interest in participating after being approached for recruitment, the study information sheet will first be reviewed with participants recruited in person or by phone by a member of the site study staff. Participants will be given the opportunity to ask questions prior to the consent

process. Afterwards, site study staff will confirm verbal consent with the participant and proceed to scheduling the interview.

Verbal consent will be confirmed again by the Yale researcher prior to the interview session as well. For Spanish-speaking parents/caregivers, the consenting process will be completed either with a Spanish-speaking site study staff or a non-Spanish speaking site study staff accompanied by a translator.

5. Study Methods/Procedures

8. Study Procedures

Schedule Table

	Day -30	Day 1	Month 1	Month 6	Month 12	Month 18
Clinic randomization	X					
CDS tool launch		x				
CDS tool training			X			
EHR data query		x		X	x	x
Clinician survey	X			X*		
Clinician interviews/focus groups	X			x**		
Parent/caregiver interviews					x**	x**

*Survey expected to stay open up to three months

**Interviews/focus groups will continue until thematic saturation is reached

1. Data Collection

We will collect EHR data from all participating sites to assess:

- Measures of obesity-related care: e.g., blood pressure measurements, visit diagnoses, problem list entries, and orders placed and their relevant dates and results, including labs, medications, imaging, and referrals.

- Clinicians' utilization of the CDS tools

- Patient characteristics: age, sex, race and ethnicity, primary language, insurance type, zip code, census tract, EHR patient portal status

- Clinician-level characteristics: e.g., specialty, clinician type, patient volume and/or primary care sessions during the study period.

Using surveys and interviews/focus groups of clinicians, we will collect information on attitudes, beliefs, and practices specific to obesity care prior to and beginning 6 months after implementation. We will also collect qualitative data around how to improve the tools post-intervention.

Costs related to implementation and changes in care delivery will be gathered from study team logs and from clinician surveys.

We will explore the perceptions and experiences of parents/caregivers regarding their child's most recent well-visit with their primary care clinician, including how they felt about how the clinician discussed growth, weight, and healthy behaviors. These interviews will be primarily qualitative, with some cognitive interviewing used in pilot testing potential future survey questions. The interview guide, including questions to be piloted, is submitted for IRB review/approval with this protocol modification.

The one-on-one interviews will be digitally recorded using video conferencing software (e.g., Zoom) and then subsequently professionally transcribed by a trusted service provider affiliated with Yale. The resultant transcripts will then be thematically analyzed afterwards by the primary researcher. The audio recordings will be only stored temporarily to allow for professional transcription services to complete the transcription process and then subsequently destroyed afterwards. All electronic files (i.e. consent forms and transcripts) will be securely stored on encrypted servers belonging to the Yale School of Medicine. Access to these files will only be possible by the study's principal investigator (Dr. Mona Sharifi) and the other collaborating members of the immediate research team.

9. Method of Assignment/Randomization (if applicable)

Practices (clusters) will be randomized 1:1 using a covariate constrained randomization by site and key practice characteristics to ensure that different practice types will have a nearly even distribution between the usual care and intervention arm. We will consider the following variables for this randomization: health system, proportion of patients that are publicly insured, proportions non-Hispanic Black, proportions Hispanic/Latino, proportions non-Hispanic White, geographic location (rural versus urban/suburban), practice size/volume, and academic vs. non-academic. Since randomization will be at the practice level, but the analysis will be conducted at the individual clinician or patient level, we will assess the adequacy of the randomization by comparing baseline demographic and clinical characteristics between the two treatment groups.

10. Adverse Events Definition and Reporting

An adverse event (AE) is any undesirable and unintended negative consequence or harm suffered by a participant from participation in the study.

An adverse event (AE) or suspected adverse reaction is considered “serious” if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

For adverse events (Aes) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

> Mild – Events require minimal or no treatment and do not interfere with the participant’s daily activities.
>
> Moderate – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
>
> Severe – Events interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious”.

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by the study PI, an appropriately-trained clinician, based on temporal relationship and her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- Related – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.
- Not Related – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician’s assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

All serious and related AEs will be reported to the sIRB within 5 business days of the investigator becoming aware of the event. Non-serious AEs that have taken place with greater frequency or severity than expected should be reported to the sIRB when identified.

11. Reaction Management

Since this trial involves intervention at the practice-level to support the implementation of national guidelines for the management of pediatrics overweight/obesity, we do not expect any emergency situations or situations of induced stress above those encountered during routine clinical care at the practices for which all sites have existing systems in place.

12. Withdrawal Procedures

While unexpected, if a clinic were to exit from the site health system network during the study period, no data would be collected from that site after its exit, as it would no longer have the EHR support needed to maintain the CDS tool in the event of an EHR downtime or upgrade.

If a participant resigns from a study site during the study, their EHR utilization data will be studied until their date of departure.

While not expected, if a parent/caregiver-participant decides to terminate their participation mid-interview, we will include the responses they did provide prior to termination in our data analysis unless the participant requests otherwise.

Parent/Caregiver interviews

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, the participant may withdraw or take away their permission at any time. The participant may withdraw your permission by telling the study staff or by writing to Dr Mona Sharifi (mona.sharifi@yale.edu) at the Yale University, New Haven, CT 06520.

If the participant withdraws their permission, they will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying the participant will be gathered after the date the participant withdraws. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

13. Locations/Facilities

Table 3. Characteristics of Sites Selected for Implementation

Site	**Duke's Primary Care Network**	**CHOP's Primary Care Research Network**	**Eskenazi Health / Indiana University / IU Health**
Geographic Region	Southeast	Northeast	Midwest
States	NC	PA & NJ	IN
Range among practices in	25% - 73% 5% - 48%	14% - 74% 7% - 8%	16% - 78% 9% - 65%

Race/Ethnicity of patients, % **Non-Hispanic Black** **Hispanic/Latino** **Non-Hispanic White**	14% - 46%	9% - 65%	5% - 23%
Range among practices in % of patients covered by Medicaid	10% - 80%	10 – 73%	80% - 88%
Other characteristics of practices	3 academic; 1 FQHC; urban, suburban, & rural	3 academic; urban, suburban, & rural	9 academic and FQHCs; no rural but 8 in Primary Care Health Professional Shortage

In addition to the three above-described study sites, study procedures will also involve Yale University and University of Florida. Yale will serve as the primary coordinating site for data and study operations. Study staff at University of Florida will be involved with the intervention evaluation.

6. Statistical Design

8. Sample Size Considerations

We plan to randomize 71 clusters of 81 clinical practices (35-36 clusters in treatment and 35-36 control) across 3 sites, with an average of 10 physicians and a minimum of 1220 eligible children per practice. This was based on baseline data collected from patient visits at all primary care practices affiliated with the 3 participating health systems. All calculations were adjusted for clustering effects using an intra-cluster correlation (ICC) of 0.1 for the physicians and 0.05 for the practice. All calculations were carried out using PASS 19 (Kaysville, Utah).

Hypothesis 1. We hypothesize that the implementation of the iPOP-UP intervention package will be associated with improved adherence to guidelines among primary care practices randomized to intervention versus usual care control. With a type I error rate of 0.025 (adjusted for 2 primary outcomes), we will have > 90% power to detect at a 7-10% increase in the adherence at 6-months over a control rate range of adherence from 10%-60%, assuming at least 1 visit per individual . This is based on data from estimates provided by the 3 sites.

Hypothesis 2. We expect that patients with elevated BMI seen in intervention versus control practices will have a slower one-year increase in BMI. Data collected as part of the STAR intervention revealed standard deviations of approximately 1.8 kgs/m^2 for one-year change

in BMI. Assuming a 30% loss to follow-up ratea two-sided type I error rate of 0.025, we will have 90% power to detect differences in one-year change in BMI of about 0.35 kgs/m^2 (smaller than the observed value in our prior work.The USPSTF found the amount of absolute or relative weight change associated with moderate intensity obesity interventions was 0.85–3.3 kg/m^2 difference in mean BMI 6–12 months after starting treatment, compared with controls.[13] Thus, our sample size will allow for ample power to examine change in BMI.

Hypothesis 3 (Aim 3): We hypothesize that baseline practice and patient-level factors such as practice type, urban-rural location, and size and patient's race/ethnicity, insurance status, severity of overweight/obesity and neighborhood characteristics will be associated with the effectiveness of the intervention and implementation strategy. The heterogeneity of the practices at the participating sites and above calculations suggest sufficient sample size to examine interaction terms and to conduct stratified analyses by baseline practice and clinician characteristics.

9. Planned Analyses

Overall we will follow an intent-to-treat principle; we will analyze the practice based on the randomization and any patient who has a well-child visit in a participating practice during the implementation period will be considered a participant in the analysis, regardless of clinicians' utilization of the EHR-based CDS tools. We will present descriptive statistics for cluster and individual level characteristics. Given that this is a cluster randomized trial, we will compare baseline characteristics of participants to determine whether there are differences across treatment groups. We will adjust for individuals level covariates that are different, after taking into account multiple testing, during sensitivity analyses. All analyses will be conducted using SAS version 9.4 and the latest version of R.

For hypothesis 1 (clinical care outcomes), we will determine whether there is a difference in adherence to guidelines at 6-months for visits in the treatment and control arms. We will use generalized linear mixed models for binary outcomes, adjusting for a set of practice characteristics, which may include health system, proportion of patients that are publicly insured, proportions non-Hispanic Black, proportions Hispanic/Latino, proportions non-Hispanic White, geographic location (rural versus urban/suburban), practice size/volume, and academic vs. non-academic, and accounting for clustering of visits within physician and physician within a given practice. We will adjust for multiple testing using a two-sided, 2.5% type I error rate for each outcome and present 97.5% confidence intervals.

For hypothesis 2 (change in child BMI outcome), to make use of all data collected during the intervention period, we will analyze the %BMIp95 outcome using a linear mixed model adjusting for the covariate constrained randomization variables and the same a priori covariates as for the adherence outcome, time (month), the time by treatment interaction and clustering of individuals within practice . and repeated

measures over individuals over time. A contrast to test the comparison at the primary time point of 12 months (-/+ 3 months; utilizing "closest" measure to 12 mo) will be employed. Overall significance will be tested at a two-sided, 0.025 level and we will report 97.5% confidence intervals.

1. Secondary Objective Analyses (if applicable)

For secondary analyses, we will use the same generalized linear mixed model approaches as the primary outcomes. We will use a conservative type I error rate of 0.01 to control for multiple testing and present 99% confidence intervals.

Data from physician surveys will be presented descriptively and use generalized linear models adjusting for covariate constrained variables to compare changes in physician practices.

Table 3. **Measurement of RE-AIM and CFIR constructs**

RE-AIM construct	**Quantitative Measures**	**Qualitative Measures**
Reach: the extent to which the population included in the study reflects the target population.	Compare characteristics of practices and patients in the participating sites with all eligible practices/patients.	
Adoption: Utilization of Epic CDS tools	EHR data and Provider survey questions regarding utilization and usability	Interviews and focus groups to collect clinician perspectives on barriers to and facilitators of adoption, implementation, and maintenance Staff interviews/focus groups: closed-ended question regarding continued program delivery at the time of staff interview/focus group
Implementation: · Fidelity · Barriers to and Facilitators of implementation · Costs associated with implementation	Formal tracking of adaptations Cost analysis	
Maintenance: Proportion of sites that sustained the program after initial adoption		
CFIR constructs	**Quantitative Measure**: Organizational Readiness to Change Assessment (ORCA)[94] mapped to CFIR domains:	**Qualitative Measures**

Characteristics of Intervention	ORCA items: Evidence Strength & Quality, Relative Advantage System Usability Scale	Structured interview and focus group guides with questions and probes assessing all 5 CFIR constructs adapted from guide available at cfirguide.org
Outer Setting	ORCA items: Patient Needs and Resources	
Inner Setting	ORCA item: Structural Characteristics, Networks & Communications, Culture, Implementation Climate, Readiness for Implementation	
Characteristics of the Individuals		
Process of Implementation	ORCA item: Planning, Engaging, Reflecting & Evaluating	

2. Analysis of Subject Characteristics (if applicable)

We anticipate describing the study sample using means and proportions. Example table:

Demographic Characteristics of Patients	Overall	Health System 1	Health System 2	Health System 3
Age at index visit, years, mean (SD)				
Sex, N (%)				
Male				
Female				
Race/ethnicity, N (%)				
Non-Hispanic Black				
Non-Hispanic White				
Non-Hispanic Other				
Non-Hispanic Multi				
Hispanic/Latino				
Hispanic/Latino Milti				
Non-hispanic Asian				
Other				
Missing/not reported				
Primary Language, N (%)				
English				
Spanish				
Other				

Missing				
Primary Insurance, N (%)				
Public/Medicaid				
Private/Commercial				
Other/Self-Pay/uninsured				
Missing				
Clinical characteristics of patients at index visit				
BMI Measures, mean (SD)				
BMI, kg/m^2				
BMI %ile				
BMI z-score				
%BMIp95				
BMI Category, N (%)				
Overweight				
Class 1 Obesity				
Class 2 Obesity				
Class 3 Obesity				
Characteristics of Primary Care Clinicians				
Total number conducting index visits, mean (SD)				
Specialty, N (%)				
Pediatrics				
Meds-Peds				
Family Medicine				
Emergency Medicine				
Urgent Care				
Other				

3. Interim Analysis (if applicable)

N/A

10. Data Relevance

The data we plan to collect are directly related to the research questions by allowing our study team to assess the impact of iPOP-UP implementation in intervention vs control sites.

11. Data Coding

Data will be coded using de-identified study IDs. These IDs will include one component to indicate participant site, and a second component to indicate the individual participant. The

IDs will be linked across data types (e.g., survey, EHR, interview). The key linking study ID to any identifying information (e.g., email address collected to facilitate providing incentive) will be kept in a separate folder on a Yale-managed, password-protected server.

12. Data Analysis Tools

All analyses will be performed using SAS v9.4 or the latest version of R. Qualitative data will be analyzed using Dedoose software.

13. Data Monitoring

The study principal investigator (PI) is responsible for monitoring the data, assuring protocol compliance, and conducting safety reviews throughout this minimal risk study on at least a quarterly basis. During the review process the PI will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment. The PI and the Institutional Review Board (IRB) have the authority to stop or suspend the study or require modifications.

14. Handling of Missing Data

We anticipate loss to follow-up and missing data for children who do not present within the one-year follow-up visit window of 9-15 months. We will utilize mixed models that employ the assumption of missing at random and plan to include all available data for individuals in the model regardless of whether it is complete (i.e. has 12 month information). Further, we will explore patterns of missing data, and conduct sensitivity analyses using techniques for models that assume missing not at random (e.g. pattern mixture model).

7. Data/Specimen Handling and Record Keeping

8. Subject Data Confidentiality

Participant confidentiality and privacy are strictly held in trust by the entire study team. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

Data confidentiality procedures will vary based on data type:

Study survey data

The intervention surveys will be built on the Yale instance of REDCap. Only Yale study staff will have access to the survey data in REDCap.

Qualitative data from interviews/focus groups

Interview audio recordings and transcripts will be saved on Yale managed, password-protected servers. Interviews/focus groups will either be recorded by study staff at Yale or at University of Florida, and will be stored on institution-managed, password-protected servers.

Queried EHR data

Limited data from participants' queried medical record for analyses will be securely transferred from each site to Yale using OneDrive or another HIPAA-compliant modality that aligns with Yale's data transfer policies. Yale will manage and securely store the data from all three sites for analysis.

Clinician email addresses, queried from the EHR along with the number of relevant visits they had during the trial period, will be used for survey recruitment and for linking study IDs across data types (e.g., survey, EHR, interview). Email addresses will be kept separate from the other queried data on Yale's server.

Participants' contact information (including name and email address) will be shared with Yale study staff for survey recruitment tracking, and will be securely stored at each study site for internal use during the study. At the end of the study, all records will continue to be kept in a secure, password-protected location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data will be securely transmitted to and stored at Yale in password-protected, Yale-compliant tools such as Box at Yale for statistical analysis and scientific reporting. These data will not include the participant's contact or identifying information except as described elsewhere in this protocol. The study data entry and study management systems used by clinical sites and by Yale research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at Yale.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see https://grants.nih.gov/policy/sharing.htm). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

9. Data Quality Assurance

All data to be analyzed in this trial (EHR data, surveys, and interviews/focus groups) will be collected into instruments built by the central (Yale) study team for this study specifically. Each site will collect data into these instruments to ensure data consistency across sites.

SOPs will be written for each of the individual instruments, and staff training will be provided as requested.

10. Data or Specimen Storage/Security

Data storage/security is covered above, in the **Subject Data Confidentiality** section.

11. Study Records

Study records include participant-level program data (surveys and queried EHR data). Study staff at each site will be responsible for maintaining these study documentation, and central (Yale) study staff will be responsible for maintaining all study documentation transferred to/held by Yale for analyses.

12. Access to Source

Participants will complete the study surveys in REDCap or on paper with prompt entry into REDCap. All survey source data will remain in REDCap. Paper-based surveys will be shredded after entry into REDCap. EHR data that is queried from the sites will be transferred to Yale via Yale's preferred method of secure data transfer. These data will be transferred directly to the study data manager, who will store the data on a Yale-managed HIPAA-protected server.

13. Retention of Records

Records will be stored in accordance with Yale and NIH policies regarding data retention.

14. Data and Safety Monitoring Plan

The principal investigator is responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews throughout the minimal risk study on at least a quarterly basis. During the review process the principal investigator will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment. The principal investigator and the Institutional Review Board (IRB) have the authority to stop or suspend the study or require modifications.

8. Study Considerations

8. Institutional Review Board (IRB) Review

The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol will

require an approved IRB amendment before implementation. The IRB will have final determination whether informed consent and HIPAA authorization are required.

Study closure will be submitted to the IRB after all research activities have been completed.

Other study events (e.g. data breaches, protocol deviations) will be submitted per Yale policies.

9. Research Personnel Training

Individuals assisting with the conduct of the research will be trained on all relevant aspects related to the trial before the trial begins, and on an as-needed basis after the trial has launched. Anticipated trainings include appropriate use of the data collection instruments and trial training materials that they may present to local participants. These trainings will be led by Yale study staff virtually (e.g., over Zoom). In addition, study SOPs will be developed and proactively shared with site study staff.

10. Study Monitoring

The study principal investigator (PI) is responsible for monitoring the data, assuring protocol compliance, and conducting safety reviews throughout this minimal risk study on at least a quarterly basis. During the review process the PI will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment. The PI and the Institutional Review Board (IRB) have the authority to stop or suspend the study or require modifications.

11. Unanticipated Problems and Protocol Deviations

This protocol presents minimal risks to the subjects and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such events occur, Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or definitely related) or Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities will be reported immediately (if possible), followed by a written report within 5 calendar days of the Principal Investigator becoming aware of the event to the IRB any appropriate funding and regulatory agencies. The investigator will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project through regular study meetings and/or via email as they are reviewed by the principal investigator.

Protocol deviations are expected in this real-world implementation study of an intervention embedded into routine care delivery. We will track these adaptations using an established framework from the field of implementation science and will generate hypotheses in our summative evaluation about how these adaptations may have influenced effectiveness and implementation outcomes.[16]

12. Study Discontinuation

The principal investigator is responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews throughout the study on at least a quarterly basis. During the review process the principal investigator will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment. The principal investigator and the Institutional Review Board (IRB) have the authority to stop or suspend the study or require modifications.

13. Study Completion

The end of the study is defined as the 24-month follow-up EHR query shown in the Schedule of Activities. The PI or proxy will notify the IRB and sponsor upon study completion.

14. Conflict of Interest Management Plan

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest. All investigators will follow the applicable conflict of interest policies.

15. Funding Source

National Institute on Minority Health and Health Disparities (5R01MD014853)

16. Publication Plan

The PI holds the primary responsibility for publishing the study results. The NIH public access policy requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to PubMed Central immediately upon acceptance for publication. In addition

to presentations at national meetings and publication of results, the study PI will be responsible for ensuring that the proposed research study is registered and that information about the results is submitted to ClinicalTrails.gov. The study will be registered in ClinicalTrials.gov no later than 21 calendar days after the enrollment of the first participant. Information about the results of the study will be submitted within one year after the study's primary completion date. Any informed consent documents will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

9. Appendices

Appendix #	Title	Section	Topic

APPROVED BY THE YALE UNIVERSITY IRB 1/21/2026

10. List of Tables

11. References

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