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Patient-Clinic-Community Integration to Prevent Obesity Among Rural Preschool Children (ENCIRCLE)

Abbreviations:

AAP – American Academy of Pediatrics

BMI – Body Mass Index

EHR – Electronic Health Record

FNPA - Family Nutrition and Physical Activity

IRB – Institutional Review Board

ISO – Information Security Office

IT – Information Technology

PACO – Patient Advisory Council on Obesity

PCP – Primary Care Provider

PRO – Patient-Reported Outcome

SNAP-Ed - United States Department of Agriculture's Supplemental Food and Nutrition Assistance Program-Education

WCV – Well Child Visit

INTRODUCTION

A proliferation of family-based interventions have been developed to prevent (and treat) childhood obesity, yet only one systematic review has examined the effectiveness of preventive interventions by delivery setting.[11] This review of 139 prevention intervention studies showed that 83% were primarily school-based and provided support for a multi-level environment approach that included school, home, and community components.[11] However, evidence through 2013 was insufficient for *non-school* based interventions, thus offering no clear direction for obesity prevention for preschool-aged children.[11] Likewise, a qualitative content analysis[43] of 119 prevention studies from 2008 to 2015 reported that only 1 in 5 studies used a multi-level setting approach, and none compared the effectiveness of varied levels, further underscoring the gap regarding the need to understand the comparative effectiveness of preventive care models for preschool-aged children. This project responds to this gap by comparing the relative effectiveness of clinic, patient-clinic, and patient-clinic-community interventions to prevent obesity among preschool-aged children in rural, low-income families at high risk for obesity.

BACKGROUND AND RATIONALE

Magnitude and Persistent Health Burden of Child Obesity: In 2018, more than 2 million US children began kindergarten with obesity.[12] The US prevalence of obesity among preschool-aged children increased from 10.1% in 2007-2008 to 13.9% in 2015-2016.[30] Low family income and community-level socio-economic deprivation in childhood increase risk for obesity and overweight through adolescence.[27,31] Rural residency is also associated with higher body mass index (BMI) in childhood and increased odds for childhood obesity.[12-15] Practitioners and policy makers are cognizant of this disparity, yet rural children remain underrepresented in the literature. The preschool years are a critical period for preventive interventions as rapid gains in BMI during this period lead to early-life obesity and a substantial health burden during childhood, including poor cardiovascular and metabolic health characterized by high blood pressure, dyslipidemia, and insulin resistance,[32-35] and other adverse physical health effects such as asthma, obstructive sleep apnea, early maturation, polycystic ovarian syndrome, and non-alcoholic hepatic steatosis.[36,37] Further, children with obesity report adverse social and emotional health including lower self-esteem and health-related quality of life compared to children with normal weight status.[38] These effects during childhood are certainly problematic, but the primary public health burden is the persistence of obesity and duration of adverse effects over time. Longitudinal studies indicate that 60 to 90 percent of preschool-aged children with obesity had persistent obesity into adolescence[2,3] and adulthood.[39] Obesity that persists into adulthood has detrimental effects on health, with a significant impact on population health: based on the prevalence of obesity among children aged 2-19 years in 2016, and assuming no gains in secular trends, 57% of the US population is expected to be obese by age 35 years and will face serious co-morbidities.[40]

Rationale for targeting preschool children: Preschool children are the focal population for this project to respond to a scientific gap in understanding the comparative effectiveness of preventive intervention strategies for preschool-age children. Obesity prevention may have the greatest preventive benefit if begun early in life, before age 2 years, and there is an opportunity to meet patients where they are in clinical well child visits (WCVs) and to extend care in

community settings.[41] Risk factors for early childhood obesity may include maternal pre-pregnancy BMI, excessive gestational weight gain, curtailed infant sleep, and inappropriate bottle use among other factors[42] whereas the Family Nutrition and Physical Activity (FNPA) patient-reported outcome (PRO) screening tool is appropriate for assessing risk factors observed in preschool children (e.g., snacking, organized play).

PCP Roles and Responsibilities: The primary care provider (PCP) is the central actor in the clinic setting and responsible for adopting clinical guidelines[9,10] for obesity prevention that include BMI screening, behavioral risk assessment (nutrition, physical activity, sedentary activity, sleep), and delivering individually-tailored, family-centered preventive counseling. PCPs face decisional dilemmas that hinder adoption of these clinical guidelines,[44] with three major gaps identified: 1) what tool to use to assess behavioral risk for obesity;[9,44] 2) how to meet parent expectations for individually-tailored, family-centered preventive counseling that meets children's developmental needs;[9,10,20] and 3) the unknown efficacy of guideline implementation on obesity prevention.[10,11] The comparators address these gaps, thereby assisting PCPs in determining how best to counsel parents of preschool-aged children at risk of obesity.

FNPA Behaviors Targeted: There is general consensus that effective obesity prevention should target: 1) poor diet (e.g., consumption of sugar-sweetened beverages and energy-dense foods); 2) low levels of physical activity; 3) short sleep duration; 4) sedentary behaviors (e.g., high media use); and 5) parenting practices.[45-49] Only 16% of 119 studies reviewed in a qualitative content analysis[43] of obesity prevention studies adhered to guidance recommending that all behaviors be addressed, with media use and sleep being under-addressed. The FNPA PRO measure and risk assessment addresses all 5 behaviors (**Appendix A**) and is a valid clinical tool to identify risk factors associated with obesity[50-52] among preschool-aged children and related chronic disease indicators (adiposity measures, severity of obesity, cardiovascular disease risk, and glucose intolerance).[53-55] The FNPA risk assessment offers time efficiencies to clinicians as parents self-assess risk to allow the PCP to focus discussion on relevant, family-centered issues.

Food Insecurity: A majority of childhood obesity prevention studies have targeted populations with low-income but *no interventions* included in recent systematic reviews[11,43,56-58] have addressed food insecurity, a well-recognized moderator of obesity.[59-62] In fact, a 2018 randomized controlled trial of parents of preschool-aged children who received all 5 behavioral targets in home and community settings failed to observe differences in BMI at 3 years follow-up *except among families who were food insecure at baseline*.[63] The American Academy of Pediatrics (AAP) issued guidance recommending food insecurity screening; this is a standard social determinant of health indicator in electronic health record (EHR) systems and fully implemented at Geisinger.[64] Professional guidance highlights the role PCPs play in referring families with food insecurity to community food access resources. Recent studies evaluating the feasibility and acceptability of PCPs in this role has emphasized the importance of providing PCPs with resources to facilitate referrals and ultimately empower parents to improve food security.[65-67] Geisinger PCPs have been asked to take action by referring pediatric patients and their parent(s) to Geisinger Wellness' collaborative effort with the Central Pennsylvania Food Bank in response to heighted food insecurity during the COVID-19 pandemic. Specifically, lost wages due to job layoffs and industry closures and limited availability of food due to shortages will strain households that were food insecure while other households will become newly food insecure. Changes in food security will be evaluated as a secondary outcome across all arms.

The specific aims for this project are follows:

1. To compare the effectiveness of WCV vs. PRO WCV vs. PRO WCV + Food Care on obesity prevention for preschool-aged children from rural, lower income households with BMI-for-age and -sex > 50th percentile at baseline.
   1a. To examine the effectiveness of the interventions on the change in BMI z-score at 1-year follow-up, and on the percent of children overweight (> 85th percentile BMI-for-age and -sex) and obese (> 95th percentile BMI-for-age and -sex) at 1-year.
   1b. To examine the effectiveness of the interventions on a secondary outcome related to parents' perceptions of being involved with the PCP in preventive counseling.
   1c. To examine the effectiveness of the interventions on secondary outcomes related to home and parent factors, including food resource management and household food security.
2. To examine multi-level mediators and moderators of effectiveness of each intervention.
   2a. To evaluate whether intervention effectiveness is mediated by parent and PCP attitudes, norms, perceived behavioral control and intention to prevent obesity.
   2b. To evaluate whether intervention effectiveness is mediated by child behaviors including nutrition, physical activity, screen time, and sleep.
   2c. To explore whether intervention effectiveness is moderated by community, clinic, and home factors. Community factors include socio-economic deprivation, rurality, and parents' perception of their neighborhood. Clinical organizational climate and household income and transportation will be evaluated.
3. To identify factors influencing effective implementation at the parent, PCP, and clinic levels.
   3a. To identify factors influencing parent completion and PCP utilization of the PRO measure.
   3b. To identify factors influencing use of family-centered preventive counseling.
   3c. To identify factors influencing parent utilization of community referrals.

PROCEDURES

Research Design

A cluster-randomized controlled trial will compare effectiveness of the two interventions (Arms 2 and 3) versus control (Arm 1) on the prevention of obesity among preschool-aged children (Aim 1). Geisinger PCPs who conduct WCVs (pediatricians, family or community medicine physicians, nurse practitioners) will represent the units of randomization (i.e., clusters). Families (the eligible child and their parent)—representing the individuals to which study findings will be generalizable—will receive one of the three interventions based on the comparator assignment of the PCP who conducts the child's WCV. Participating PCPs will be randomized into an intervention arm, which entails having changes made to their EHR interface and having these changes impact all preschool-aged children for whom they provide WCV (Arms 2 and 3). The EHR changes are novel to the eligible PCPs. Families will be consented to participate in the study follow-up, but not to the interventions, which require implementation on a system level. Cluster, rather than individual-level, randomization is warranted because of the automated EHR-based intervention, because PCPs cannot be expected to change their standard

clinical practices on a patient-by-patient basis, and because their obesity-prevention practices will likely be influenced by their exposure to FNPA (i.e., "contamination" concerns). The cluster design isn't without disadvantages. This design has the potential for imbalance of the number of subjects across PCP resulting in possible imbalance at the intervention level. Also, analyses are complicated with a small number of clusters (<20). To overcome these disadvantages, we have compensated for potential imbalance in the sample size calculations. Lastly, our chosen method of analysis appropriately handles imbalance and combined with a large number of clusters, a total of 60, we do not anticipate concerns in the implementation and analysis.

A stratified design will be used to reduce the imbalance of covariate distributions between intervention arms. Prior to randomization, PCPs will be stratified based on the type of clinic in which they practice (Pediatrics versus Community Medicine) and case load (number of annual WCV conducted among the target population; low volume (< 52 WCV/year) or high volume > 52 WCV/year), as heavy patient volume can disrupt workflow and may affect intervention delivery.[99,100] Since stratification can only address a limited number of potential confounders, initial analyses will examine other covariates known to influence clinical interventions and/or childhood obesity such as parent BMI, child baseline weight status, biological sex and race/ethnicity.

CORRECTION: Per discussion with the study team and PCORI in October 2022, it was observed that stratification details are an error. Per study documents, in August 2020 the study team observed that all but one pediatrician had a volume <52 WCVs in 2019, the past year, and Year-to-Date assessments; conversely, all Community Medicine providers had <52 WCVs . Therefore, 2 strata characterized: Pediatricians and Community Medicine. The Community Medicine providers were further stratified by those with <32 WCVs/year and those with >=32 WCVs/year to align with clinic eligibility criteria: "Eligible clinics will have ≥1 PCPs with at least 32 qualifying well child visits annually for children aged 20 to 60 months, ≥50th BMI-for-age and -sex percentile."

Following randomization, PCPs' assignment to 1 of the 3 comparators will be revealed to PCPs. However, PCPs will be blind to whether individual patients are participating in the study follow-up. For Arm 3, post-WCV referrals to Food Care will be aided by a research assistant (not blind to PCP assignment) who will discuss the education program option with enrolled participants and document the referral in the child's EHR. Thus, at the point of the enrolled patient's baseline WCV, all PCPs will be blind to participant identity; only at follow-up visits will PCPs be aware of who is enrolled in Arm 3. Per practice guidelines and insurance schedules, WCVs are scheduled at ≥12-month intervals; however, children could return in the interim for acute care and a PCP may observe a child's prior exposure to a group through progress notes. Theoretically, the PCP providing acute care could "contaminate" the parent-child dyad by discussing healthy lifestyle behaviors, but pragmatically, the contamination risk is low due to high likelihood of maintaining care with the PCP who provided the WCV and low likelihood of a PCP discussing such behaviors during acute care visits (based on PCP and parent reports). Nonetheless, progress notes from child participants' EHR will be monitored over the study period to fully capture the dose of preventive counseling. To further reduce bias, study investigators, biostatisticians, and the project coordinator (responsible for collecting study questionnaires) will be blind to PCPs' intervention assignment. The project manager and data analyst will not be blind to intervention assignment, due to participant and data management responsibilities.

Study Population

Human subjects include Geisinger pediatric patients, and their parents/caregivers, from Geisinger Pediatric and Community Medicine clinics. Human subjects also include Geisinger Pediatric and Community Medicine providers who meet study threshold for volume of annual well child visits.

Inclusion criteria for child participants include:

- Age (20-months to 59-months, 29-days old)

If the child is <24 month of age, then eligible if greater than or equal to 50th percentile for BMI-for-age and -sex at any visit (WCV, acute, etc.) since age >12 months or at enrollment.

If child is > 24 or <27 months of age, then eligible if greater than or equal to 50th percentile for BMI-for-age and -sex at any visit (WCV, acute, etc.) in the prior 12 month period or at enrollment.

If child is >27 months or <60 months of age, then eligible if greater than or equal to 50th percentile for BMI-for-age and -sex at any visit (WCV, acute, etc) in the prior 15 month period or at enrollment.

This study uses the World Health Organization (WHO) growth standards for inclusion criteria and the primary outcome, BMI z-score (https://www.who.int/childgrowth/standards/en/).

- Parent commitment to participate in 18-month study
- Plans to attend scheduled WCV and recommended follow-up WCV in 12 months
- No plans to move or change health systems in 2 years
- Parent age ≥ 18 years
- Parent is English-speaking
- Household is considered lower-income (i.e., eligible for or receiving Special Supplemental Nutrition Program for Women, Infants and Children [WIC], Supplemental Nutrition Assistance Program [SNAP], Temporary Assistance for Needy Families [TANF], Medicaid, or Children's Health Insurance Program [CHIP]), screens positive for food insecurity, National School Lunch or Breakfast participation, has picked up school lunch or breakfast at curbside during coronavirus, or has experienced job disruption due to coronavirus.

Child exclusion criteria include:

- Children who attend their regularly scheduled WCV via telemedicine
- Another child in family is participating
- Pre-existing medical exclusions (cancer, type 1 diabetes, major developmental delays such as autism)
- Parents with self-reported major depression will be excluded
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Potentially eligible child patients will be initially screened and identified using an Electronic Health Record query for patients meeting the study inclusion/exclusion criteria. Potentially eligible participants will also be screened in-person when they present at clinic for care; by

phone interview if the child has a scheduled well child visit but does not have an established history in the electronic health record (e.g., new patient); or online self-screening initiated by the parent/guardian (i.e., in response to seeing recruitment flyer, MyGeisinger message, social media ad, etc.).

Participant Enrollment

Table 1. Projected Enrollment

1. Estimated number of potentially eligible study participants (determined by Electronic Health Record):	5,438
2. Total number of study participants expected to be screened:	5,438
3. Total number of study participants expected to be eligible of those screened:	3,643
4. Target sample size (use same number stated in milestones):	2,025
5. If applicable, total number of providers that will enroll participants:	100
6. Projected month first participant enrolled (month after project initiation):	Month 8
7. Projected month last participant enrolled (month after project initiation):	Month 35
8. Projected rate of enrollment (anticipated number enrolled per month of enrollment period):	169
9. Estimated percentage of participant dropout:	10%

Study Procedures

Geisinger Community Medicine and Pediatric Service Line leadership will attest to the inclusion of clinic sites to engage in the study. Eligible clinics will have ≥1 PCPs with at least 32 qualifying well child visits annually for children aged 20 to 60 months, ≥50th BMI-for-age and -sex percentile. Geisinger PCPs who qualify for participation in this research will be informed of the study asked to participate in a FNPA training (in-person and via Microsoft TEAMS) and complete study questionnaires referenced in **Appendix B** (clinic and PCP items)**.** Baseline questionnaires will be self-administered and collected via hard copy (at training) or via RedCAP (following TEAMS training). For the purpose of implementation evaluation, PCPs will also be asked to complete follow-up questionnaires at 12 and 20 months; questionnaires will be administered via RedCAP. Attendance at a training session will be seen as implied consent to participate in the research.

Randomization will occur at the PCP level. PCPs in Arm 1 will be asked to provide usual well child visits. PCPs in Arms 2 and 3 will be asked to provide standard well child visits at Geisinger which include the FNPA screening tool. FNPA has been recognized as standard of care in some Pediatrics and Community Medicine clinics since 2013. FNPA implementation at Geisinger has occurred in phases to gradually scale-up and simultaneously allow for rigorous testing of efficacy and effectiveness. In this study, PCPs in Arm 1 will be considered "wait-list" and will be trained on FNPA, consistent with standard of care, but the FNPA screening tool will be delayed and phased into care after the intervention period is complete. All PCPs trained but having less than 32 qualifying WCVs will be randomized but excluded from primary outcome analysis. This offers the advantage of concurrently training all PCPs within clinics on standard of care. FNPA has been adopted as standard of care because it facilitates the expected and usual clinical practice of assessing behavioral risks and offering patient-centered preventive care at well child visits. Although all PCPs in clinics will be trained on FNPA, the potential for contamination across arms is low because PCPs in Arm 1 will not have access to the automated

FNPA for any of their patients until the intervention is complete. PCPs in Arms 2 and 3 will have FNPA all well child visits and be unaware of which children are study participants. There will not be documentation of the Food Care intervention for Arm 3 in the participating child's electronic medical record, thus PCPs will be blind to knowing if they are in Arm 2 or 3 and whether the participant is eligible for Arm 3 Food Care.

Potential child participants will be identified 3 ways: 1) via an electronic medical record data pull performed by a data broker in the Obesity Institute; 2) in the clinic waiting room (pilot); and 3) self-referral. In the electronic health record pathway, the data broker will apply inclusion and exclusion criteria to identify qualifying PCPs and patients that have upcoming well child visits scheduled with a participating PCP. All identified, and potentially eligible participants will be simultaneously sent a recruitment letter, an email (if available), and MyGeisinger message (if available) which provides information regarding the study, participation, how to opt-out, and a study URL and/or QR code to self-refer, and that if they have not contacted the study team, someone will be reaching out by phone to assess interest (≥10 days). The recruitment letter and email for participants will encourage parent proxy enrollment in the patient portal to facilitate communications and scheduling, completion of pre-visit questionnaires in the patient portal (consistent with standard practice), attendance at routine, annual well child visits, and the potential for the intervention to include a health coach and grocery store visit (after the WCV is complete). A reminder email will be sent 3-5 days after the initial email. Participants can completely enroll in the study if they click on/enter the URL/QR code in the email, letter, or portal because all the study enrollment information will available. In the electronic pathway, participants can call or email us with questions they have about the study. After 10 days from sending the letters, the study team will call the participants who did not yet respond electronically and did not opt out. When the potential age-eligible participant does not have history in the electronic health record (e.g., new patient) and the child has an upcoming scheduled well child visit, the study team will call and send an email, letter, and/or MyGeisinger message (if available). When possible, parent/guardians will be provided with 10 days between written or electronic communications and telephone calls; however, calls may occur in a shorter window of time to give the parent/guardian ample opportunity to learn about and participate in the study. This modification acknowledges that patients may be scheduled for a well child visit within a day of calling for an appointment.

Once contacted by phone, the research team will discuss the study with the patient's parent/caregiver, and if the family is interested, obtain informed consent to participate in survey data collection at baseline, 6 months, and 12 months as well as data extraction from their electronic health records. The participant can access the same information by clicking on the URL and/or QR code. Recognizing that participants may experience connectivity difficulties online, the study team will follow-up with participants who start but do not complete the online screening process. E-consent was utilized as the primary consented method for this project until the study team corrected an inefficiency related to the impractability of collecting written consent using a 3-step remote process (call → email → eConsent sign). A waiver of HIPAA authorization was requested to alter the requirement for a written signature and date and replaced by the study team reviewing the consent language with the participant during the screening call and obtaining verbal informed consent. Participants who consent verbally receive a study information sheet and the study team maintains a log of consent authorization. All participants

will have an equal opportunity to participate in this research and will be targeted through multiple attempts using a standard protocol. Telephone calls for recruitment purposes will be performed by Geisinger' Survey Research and Recruitment Center (Call Center) in a secure location housed at the Geisinger Center for Health Research, and accessible only to trained, approved staff.

Novel strategies will be piloted to evaluate the effectiveness of reaching participants as we have been unable to reach more than 40% of participants with electronic/mail/telephone strategies. These strategies will be layered on top of the existing EHR-Identified, electronic/mail/telephone strategies including- in-clinic/in-person, clinical flyer/generic social media, and snowball recruitment. In the pilot in-clinic pathway, potential participants will be screened when they arrive to the clinic. Potential participants will see the study infographic, receive a study flyer, and be screened in the waiting room prior to the well child visit. Enrollment will be contingent on the child meeting inclusion criteria (i.e., BMI will not be known). The study team staff could obtain objectively collected measures from the child's historical electronic health record (before the current WCV) or from the clinic staff. Immediately following the clinical visit, parents of eligible children will complete informed consent and complete baseline questionnaire. Children will be provided with a coloring book and crayons (or other similar materials) to allow the parent time to complete questionnaires. The baseline questionnaire will be broken into 2 parts and evaluated for feasibility of implementation at baseline. For example part A will be brief (5 minutes) to capture parents' attitudes before the visit and allow just enough time for completion before the patient is roomed; part B will be longer (15 minutes). Given that parents may want to leave the clinic immediately following a WCV, especially if a young child is crying after vaccination shots, the study team will follow-up with the parent/guardian to complete consent and baseline data collection following the completed WCV. The in-clinic pilot will occur in less than 5 sites. Workflows will be established with clinical staff to not disrupt care. The in-clinic/in-person recruitment strategy was pilot-tested but discontinued due to low response. In the pilot self-refered pathway, potential participants will respond to to a study flyer posted in the clinic and in social media (e.g., Facebook and/or Instagram). There will be a QR code that sends participants to a self-screening site, similar to the email recruitment strategy. Potential participants and participants will be encouraged to refer a friend using the study flyer. The snowball strategy involves sending a letter and/or email to existing participants asking them to share the opportunity to participate in the study with someone who might be interested. Participants will be provided with a URL, QR code, phone number, email, and study flyer to share with their contact(s). The social media strategy will also utilize patient stories as a potential recruitment method. Results from the pilot efforts will be rapidly evaluated to scale up effective strategies for the remaining study period.

Participant recruitment is based on the Arm of the PCP the child is scheduled with for the upcoming WCV. The patient is recruited up to 6 months prior to the scheduled visit with the intent of being assigned to the treating provider's condition or following a completed WCV. Participant assignment follows PCPs random assignment at the point of scheduling and initial recruitment. The study team expects that most of the participants will see the PCP that they are originally scheduled with or a PCP in the same Arm. However, the study team anticipates that up to 8% of partipants will not receive allocated treatment (i.e., child's WCV is conducted by a PCP in different arm than scheduled) due to absences or unplanned events. In response to this

challenge, the study team will monitor the patient's schedule up to 16-days prior to the WCV. At that point, the study team can modify PRO data collection to the scheduled provider's condition. Two alternate scenarios are planned in the event that the treating provider changes within 16 days of the WCV. First, if a participant is scheduled with an Arm 1 (no PRO) provider but sees an Arm 2/3 provider (PRO view), the participant still has the opportunity to complete PRO in the waiting room because office staff are cued to close open care gaps (PRO) and the participant is reassigned to the treatment provider. Second, if a participant is scheduled with an Arm 2/3 provider (PRO opportunity pre-visit) but sees and Arm 1 provider (no PRO view), then the participant is reassigned to the treating provider. Participants will be retained for intent-to-treat analyses regardless of the PCP Arm at the point of care (WCV). Participants in scenario 1 will be excluded from a per protocol analysis due to limited FNPA exposure and participants in scenario 2 will be excluded from a per protocol analysis due to no opportunity to discuss PRO with the clinical provider. Arm 2 and 3 participants are interchangeable from scheduling assignment through the point of care because the condition is the same through these cases.

Participants in Arm 1 will receive their usual care well child visit with their Arm 1 PCP. They will be asked to complete study questionnaires and return to the same PCP for an annual well child visit (ideally 12 months, 1 day to 17 months, 364 days from baseline well child visit). Participants in Arm 2 and 3 will receive the FNPA screening tool, consistent with standard of care, and asked to complete study questionnaires and return to the same PCP for an annual well child visit (ideally 12 months, 1 day to 17 months, 364 days from baseline well child visit). In December 2020, Geisinger implemented EPIC® standard which included previsit questionnaires, a new feature in the standard licensed software. Changes for participants enrolled in MyGeisinger include the launching of pre-visit surveys at 14 days (rather than 16 days) prior to scheduled visits. The vast majority of study participants are dually enrolled in MyGeisinger and will receive visit reminders via text. Geisinger has requested that EPIC® add functionality for a 'notification tickler' text that will prompt MyGeisinger users to complete standard of care pre-visit questionnaires (e.g., FNPA) before visits to save time during check-in. Recognizing that the system intends to implement multiple reminders for standard of care questionnaires, the study team requests advance implementation. The rationale: 1) to ensure that a majority of participants will have similar experience to data collection prompts as more than 80% of the sample is yet to be enrolled but the timeline for EPIC® modifications is unknown but likely to occur before study enrollment is complete; and 2) to ensure opportunity for data collection as participants have been refusing to complete pre-visit surveys on Geisinger devices (iPad) in the waiting room, a new phenomena during the COVID pandemic, likely explained by fear of transmission despite clinic staff offering devices and ensuring their cleanliness. Participants in Arms 2 and 3 and who are dually enrolled in MyGeisinger, will receive 3 text message reminders to complete pre-visit questionnaires prior to the well child visit. Sequential reminders are only sent to participants with incomplete questionnaires.

Arm 3 participants will be contacted after the well child visit is complete and offered a referral to the Geisinger Steele Institute Wellness Program (Health Coaches) for the Choose Health LA: Parent Training Program, and a grocery store tour (after the 3rd health coach call as learning activities are complementary). The Parent Training Program will be delivered as 6 individual sessions via virtual video (e.g., TEAMS, GoToMeeting, Zoom, Apple FaceTime, Google Duo) or telephone, or video (when participant fails to attend scheduled synchronous

session), spread throughout a 26-week intervention period. These telephone calls may be recorded to conduct fidelity monitoring in relation to the intervention delivery. The Geisinger Wellness staff will deliver the Choose Health LA curriculum to the study participants as part of their existing roles and responsibilities to advance population health outcomes through outreach and education to patients who screen positive for food insecurity and other social determinants of health. The intent of evaluating the implementation of the Choose Health LA curriculum by Geisinger Wellness is to understand how the curriculum is adapted by staff locally, to inform institutional sustainability, and to inform future implementation and dissemination. The number of Geisinger Wellness staff implementing the curriculum is limited (n=1, 1.0 FTE) and thus, there is no intent to systematically understand how the health coach, per se, affects implementation or outcomes. During the course of the study, other Geisinger staff will be trained to deliver the curriculum if the volume of participants who agree to receive education in Arm 3 exceeds the capacity of existing Wellness 1.0 FTE (or if there is staff turnover). However, there will not likely be more than 3 coaches total in the course of the project, certainly too few to systematically study, and thus will not change the intent of evaluating the implementation of Arm 3.

Trained study team dietitians may function in the role of the Health Coach in the event of staff shortages; otherwise, the dietitians have no other role on the project. For the purpose of implementation evaluation, Health Coach will be asked to complete questionnaires at baseline, 12- and 24-month follow-up periods. The grocery store tour will be delivered by trained, in-store nutritionists across the study region (e.g., Giant Foods, Wegmans, Weis Markets). Grocery store tours are usual practice for in-store nutritionists. To ensure participants are able to receive the grocery store tour trainings, they will be offered both in-person and virtually (utilizing TEAMS, Zoom, etc.) and conducted by the grocery store nutritionists. Patient-preference for delivery (in-person vs. remote or a hybrid) of the Cooking Matters® grocery store tour will be considered to promote participation in the event that social distancing precautions remain in place or participants have transitioned to online grocery ordering. Share Our Strength's Cooking Matters® campaign is increasing efforts to deliver digital content through Zoom, Facebook Live, and YouTube and other platforms to support families with strategies and skills. The study team will collaborate with the in-store nutritionists across the region to utilize newly developed digital content to supplement in-store tour learning activities. Importantly, grocery store nutritionists have also started to transition to virtual care for their customers, thus a transition to digital delivery is consistent with their practice. Participants may receive educational materials by email or postal service mail, per participant preference. In an effort to best track completion of grocery store tours by Arm 3 participants, the study will implement a short Grocery Store Tour questionnaire for participants to complete. This 3-question questionnaire will ask the participant to report if they attended a tour, the grocery chain the tour occurred at, and whether the tour was in-person or online.

The active intervention in Arm 3 will last a total of 6 months with active participant involvement. Participant satisfaction will be collected following the first and last calls with the health coach. Following the 6-month intervention, follow-up measures will be collected at 6 months. For all arms, data will be extracted from the EHR during and following the 12-month period to assess the implementation and impact of the intervention on child BMI.

Participant recruitment is based on the Arm of the PCP the child is scheduled with for the upcoming WCV or completed WCV. Participant assignment follows PCPs random assignment at the point of scheduling and initial recruitment. The study team expects that most of the participants will see the PCP that they are originally scheduled with or a PCP in the same Arm. However, the study team anticipates that participants will be lost when the child does not receive allocated treatment (i.e., child's WCV is conducted by a PCP in different Arm than scheduled) due to absences or unplanned events. Loss of thse participants is accounted for in the sample size for per protocol analyses. However, the primary BMI outcome analysis is an intent- to-treat analyses and will include these children, regardless of the PCP's Arm at the point of care (WCV).

Participants will be reminded to complete study consent, questionnaires, study measures, health coach calls, and grocery store tour via follow-up phone calls, emails, MyGeisinger patient portal, and text messages sent utilizing the internal Geisinger process that is currently leveraged to send appointment reminders to patients. This is an approved platform by ISO.

All data (EHR and patient-self report) will be kept behind the Geisinger firewall on password-protected servers that are only accessible to Geisinger IRB-approved staff. For data shared with PSU, all Geisinger IT/ISO policies regarding secure transportation of patient data will be followed. Data shared outside Geisinger will be stored in a secure location to ensure patient data is protected.

Participant Compensation

Parents/guardian participants will receive a $50 check per survey completion at baseline, 6 months, and 12 months for a total of $150, if the patient completes all 3 surveys, they will receive an additional $50 for a total of up to $200. Geisinger providers will not be compensated for completion of study questionnaires. Participating clinics will receive a stipend of $500-$1,000 depending on number of qualifying PCPs as those with a higher number may experience greater disruption to workflow with added burden of collecting patient-reported data. Note that all clinics now collect patient-reported data with varied workflows and technology resources (e.g., tablets, kiosks) and this burden is expected to be minimal.

Participant Withdrawal

Participants who choose to withdraw from the study will not be contacted for further survey data collection. In addition, for participants in Arm 3, if the choice is made to withdraw, they will not receive any further contact from their health coach. Participants may be withdrawn from the study by an investigator if they choose to switch providers or leave Geisinger. All data collected up to the point of withdrawal may be used for analysis purposes.

Data Management Procedures and Confidentiality

Data collected as part of this study will be keep indefinitely for future analysis such as potential follow-up analysis to determine long-term study impacts, and for use in grant planning to pursue additional research-related activities. These data will be stored on stored locally on Geisinger encrypted, password-protected servers behind the Geisinger firewall. Only trained study personnel who adhere to the National Institutes of Health (NIH) policies on the protection

of human subject participants in research, and are approved by the Geisinger IRB, will have access to study data.

Questionnaires will be administered using REDCap, which will also be used to manage and store related data elements (e.g., participant tracking). Data from paper versions of self-administered questionnaires will be manually entered into an electronic dataset. Double-entry and verification steps will be taken to reduce potential for human error. Electronic questionnaire data will be stored internally on Geisinger's secured network and access to REDCap will be restricted to approved study personnel. Study participant information will not be released to any party without the participant's permission. RedCap access occurs over password-protected channels only accessible via the use of an authenticator. Data is stored locally on Geisinger encrypted, password-protected servers behind the Geisinger firewall.

In the event that data would be transferred outside of Geisinger, it would be done using a secure file transport system maintained by Geisinger IT/ISO. This secure transport method would allow access only to approved IRB study staff with unique usernames and passwords required to access the site.

Data Analysis/ Statistical Considerations

Table 2. Estimated Sample Size per Randomization Arm

Effect size*	# Physicians per group	# participants per Physician	Total N per group
0.20	**20**	**32**	**640**
0.20	25	25	625
0.25	20	19	380
0.25	25	15	375

*Cohen's d: mean difference / SD

Sample Size and Power

Our preliminary data comparing the change in BMIz between WCV vs. ***PRO WCV*** yielded a difference of 0.05 units.[6] This corresponded to an effect size (Cohen's d) of approximately 0.20 of a standard deviation. Additionally, based on our preliminary data and the literature, we estimate the intra-cluster correlation (ICC) to be 0.005 to account for the clustering of participant families within PCP. We recognize that participants may be lost to follow up during the course of the study or that we will not recuit equal number of participant families across all PCPs. Therefore, our sample size calculations further assume a coefficient of variation (COV) equal to 0.25 to account for this potential imbalance. This parameter being greater than 0 (i.e., equal sample size across clusters) increases the required sample size. Lastly, to account for two *a priori* statistical comparisons in Aim 1 (***WCV*** vs ***PRO WCV***, ***WCV*** vs**. *PRO WCV* + *Food Care***), the significance level is set at 2.5%. **Table 2** reports the required sample size for enrollment under the stated assumptions. All calculations assume 80% power and an overall significance level of 5% such that each of the two comparisons will be made at the 2.5% significance level.

The software PASS v15 was used for all calculations, specifically the module for cluster randomized trials for two means. Table 2 reports the required sample size for enrollment under the above stated assumptions (reproduced in this response). We also varied the effect size to additionally include 0.25 and using 20 and 25 PCPs per arm to understand how varying-the

parameters affected the sample sizes. For example, assuming an effect size of 0.20, ICC of 0.005, COV of 0.25, 80% power, and 0.025 significance level, the study would be required to enroll 28 participant families per PCP per arm for a total of 560 families per arm. However, we further inflated the sample size to account for 7% of participants not receiving allocated treatment (i.e., WCV completed by a PCP in a different Arm than scheduled) and a 10% dropout at 1 year. This yields a sample size of 675 per arm or, with rounding, 33 families per each of 20 PCPs, for a total of 675 per arm (N=2,025 across all three arms).

The study will have 80% power to detect an effect size of 0.20 with 20 PCPs per randomization arm and 33 participant families per PCP, for a total of 2,025 across all three groups in Aim 1. If we are able to obtain more PCPs, then we can reduce the number of families. Also, if the effect size is larger than we observed in our preliminary work,[6] then the study will have > 80%. It is recognized that to assess for mediation and moderation that a larger sample size is required and thus, we do not expect to have a large power to detect these effects. Thus, Aim 2 results will be descriptive in nature. Given that multiple recruitment strategies are simultaneously in place, and the rate of enrollment is about 10 participants/week when 95% of the targeted sample has been achieved, the study has a buffer of 15 additional participants who may be in latter stages of recruitment when the sample is achieved. In other words, up to 2040 participants may be enrolled.

Outcomes

The primary child-level outcome is the 1-year difference in change in BMIz between study arms using World Health Organization growth reference standards. BMI values will be obtained from Geisinger clinical care visits, documented in the EHR. Values obtained at well child visits (preferred), clinical visits, or self-report during the study period, ideally 12 months, 1 day apart will be utilized but values from baseline WCV to 9 to 18 month follow-up may be used to assess the primary outcome. This primary outcome is chosen because it reflects the difference in the effectiveness of each intervention versus standard of care in preventing obesity among a high-risk population of preschool-aged children. The difference in the difference between groups is chosen because the intervention is randomized at the PCP and not the patient-level. Parent self-report of child weight and height is added to supplement primary outcome data given unprecedented changes in pediatric care secondary to the pandemic. Specifically, the availability of WCVs has decreased due to staff turnovers yet the demand has decreased as families delay or forgo preventive care. To optimize follow-up height and weight data collection, parents of children without a clinical BMI at about 1-year post-baseline WCV, will be encouraged to complete the child's follow-up WCV, per clinical schedule, or to visit the clinic for height and weight measures. Among this subset of the study population (implemented in September 2022), parent self-reported data about child's height and weight will be collected before the WCV or clinic visit.[153-156] Parents will be asked whether the self-reported data are estimates or measured at home.[153-156] Among a smaller subset, the self-reported data will be compared with objective height and weight collected in usual clinical care. Concordance between the parent self-report and clinical measures will be evaluated for validation of self-reported data. If the variation among self-report with objective clinical measures is acceptable, self-reported data may be used as follow-up measures. To determine if the variation is acceptable, variation will be compared to the literature to inform analytical strategies for using supplmental parent-reported data in the absence of clinical measures.[153-156] The use of self-reported measures is anticipated for studies

conducted during the pandemic and will likely be found in emerging and current literature.[157] While many adiposity outcomes could be used, this outcome will facilitate interpretation of the relevance of the findings among PCPs, health care administrators, policy makers, and researchers who pursue future systematic reviews of delivery care models to prevent childhood obesity. Nonetheless, BMIz can be too restrictive to evaluate success and may not be meaningful to parents or clinicians.[122] Therefore, we will also evaluate the proportion of children overweight and obese at 1-year follow-up per CDC guidance and definitions (https://www.cdc.gov/obesity/childhood/defining.html), difference in raw BMI and difference in BMI50 between study arms, and BMIz extended.[158-160] Patient stakeholders to the project (Patient Advisory Council on Obesity, PACO) identified meaningful secondary outcomes and PCP's identified mediating pathways to inform steps that parents and PCPs can take together to prevent obesity. Specifically, findings will help to inform parents of what they can realistically expect for their children if they pursue standard of care WCV, complete the PRO risk assessment and engage in discussion with their child's PCP, or take these steps and participate in a community-based nutrition program. PCPs would understand benefit of utilizing FNPA, training, and intentionally engaging parents in counseling on childhood obesity prevention.

Analytic Plan

During the start-up of the study we will develop a formal Data Management Plan to document how data will be collected, organized, stored, as well as a statistical analysis plan. Descriptive statistics will include evaluation of all data for underlying distribution and summary statistics, using means with standard deviations and medians with interquartile range for continuous variables, and frequency with percentages for categorical variables. The data will be summarized for all patients enrolled and will be stratified by randomization arm and study time point. We will assess the quality of data, evaluating outliers and patterns of missing data using graphs such as histograms and stem-and-leaf plots. Bi-variate analyses will be used to assess differences in patients (e.g., parent BMI, child biological sex, baseline BMI) between randomization arms. Since it is not recommended to perform inferential statistics to assess balance of baseline participant, family, community, and physician factors in a randomized study, we will use standardized differences.[103] Any standardized difference > 0.10 will be considered unbalanced and, thus, a potential confounding variable. We will also follow the CONSORT[104] extension to cluster randomized trials when reporting results.

As data is collected from participants as part of this research study, in an effort to facilitate additional analyses, the Geisinger study team plans to share a de-identified data set with PSU. This data set will be shared utilized Geisinger IT-approved methodologies (Secure Transport, e-secure, etc.) to ensure that patient data is protected. These data will be stored at PSU in a secure network location that is only accessible to PSU study staff. These analyses will assist in exploring additional study research questions that may arise.

Aim 1. The primary outcome variable is change in BMIz at 12 months. BMI*z* is the most widely used obesity-related outcome per systematic review and thus was chosen for comparability with prior literature.[11,105] The primary analysis will follow the "intention-to-treat" principal. That is, all participants enrolled will be analyzed according to their group assignment at the point of care (WCV) regardless of intervention received and compliance. Analyses will

take into account the clustered nature of the study design. To test the Aim 1 hypothesis that participants will have a lower change in BMIz (and secondarily, changes in BMI, BMI50, BMIz extended) in Arms 2 and 3, as compared to Arm 1, mixed linear models[106,107] with restricted maximum likelihood estimation will be fit. The models will include a random effect for PCPs and will be assumed to follow a Gaussian distribution. These analyses will adjust for the stratification factors used in the randomization scheme and any baseline variables found to vary across intervention arms as identified above. Contrast statements will be written as functions of the estimated regression coefficients to estimate the effect of the interventions compared to standard WCV using a two-sided alpha of 0.025 to account for multiple testing. Model assumptions will be examined (e.g., QQ plots to assess normally distributed residuals) and of the underlying Gaussian random effect distribution. Secondary analyses will estimate the effectiveness of the interventions on the percent of children overweight and obese ($\geq$ 85 percentile of BMI and $\geq$ 95 percentile of BMI) at 12 months. A similar strategy will be employed using a generalized linear mixed model assuming a binomial distribution for the outcomes. These models will treat the binary outcomes as measured from the 12-month visit. Analysis of secondary outcomes in Aims 1b and 1c (involvement in preventive care, parent and home factors) will follow the same strategy as described above. Due to lagging enrollment, the study modified data collection for secondary outcome in specific aim 1b- involvement in preventive care- just after 50% enrollment was reached. The timing of this outcome measure was changed from pre-visit only to pre- or -post visit to allow for families to enroll and complete baseline data collection after a completed WCV. As there are complementary analysis methods for cluster randomized trials, we will also fit Bayesian random effect models[108-110] for continuous and binary outcomes. Each model will use an inverse gamma prior for the cluster random effect variance parameter.[111] We will note any differences in the effect estimates across methods.

Aim 2. The primary outcome variable is the same as in Aim 1, change in BMIz at 12 months. Aim 2 involves the assessment of mediating and moderating effects of PCP, parental and child behaviors (see list of variables in **Appendix B**). For a variable to be considered a mediator it must be associated with and in the casual pathway between the intervention and outcome. Therefore, we will first fit mixed linear models to each hypothesized mediator as dependent variables following the approach described in Aim 1. We will then fit similar models with BMIz as the outcome and each potential mediator as independent variable. Any variable found to be associated with intervention and BMIz will be considered a potential mediator variable. Our list of candidate mediator variables is measured at both the subject (parent and child) and cluster levels (PCP). To appropriately fit models with mediation at different levels we will rewrite the mixed models of Aim 1 as multilevel structure equation models (MSEM)[112] to include the variables in the analysis. Results will be expressed as total, direct, and indirect effects as estimated from the model. Moderation will be assessed using the MSEM framework.[113] In Aim 1, we will also fit complementary Bayesian models to assess robustness of effect estimates. Aim 2 outcomes may be evaluated using secondary outcomes including raw BMI, BMI50, and BMIz extended.

Missing Data Considerations. We will minimize missing data by querying the EHR for anticipated and scheduled 1-year follow-up WCVs, sending reminders to each participant to schedule and attend appointment, and reminding participants of 1-year follow-up study questionnaires. Missing data, however, are inevitable in a longitudinal study due to dropout and

nonresponse to study questionnaire items. We anticipate that no more than 7% of randomized subjects will not receive allocated treatment and 10% of randomized subjects will fail to complete the study;[63,90,115] but reasons for loss at point of WCV care and dropout will be documented. Before proceeding with primary analyses, we will characterize patterns of missingness using exploratory analyses to provide insights into how to handle the missing data. Participants with missing data will be compared to participants with complete data to ensure there are no differences. Depending on the amount of missing data, we will use a non-parametric missing data imputation method based on random forests.[116] This method has been shown to perform as well as or better than more traditional methods of imputation, and it has the advantage of imputing both continuous and categorical data. By using random forests, we can capture non-linear relationships and interactions present in the dataset that may otherwise be missed when using a different method. At least 5 complete datasets will be created and combined using the methods of Rubin.[117]

Heterogeneity of treatment effect (HTE). HTE analyses are incorporated into Aim 2 when examining moderator effects. Additional sub-group analyses will be performed by child sex (males, females) and baseline BMI weight category (overweight, obese). These sub-group analyses will employ the same models as described in Aim 2.

Aim 3. The **RE-AIM framework**[29] will be used to evaluate the interventions' reach to the target population and subgroups (e.g., by provider type, those with food insecurity and hunger), comparative effectiveness, adoption by PCPs, implementation fidelity and barriers, and maintenance of intervention components over time, so as to inform translation of this study into practice.

EXPECTED RISKS/ BENEFITS

Potential Risks

The greatest potential risk to participants in this research is a loss of confidentiality. To minimize the risk of loss of confidentiality, all data collected as part of this study will be stored on the Geisinger password-protected network only accessible to IRB-approved study staff. Participants will also be assigned a unique study ID for data collection. In the event that any data would be shared outside of Geisinger, it would be done using an IT-approved secure transport method to ensure data security is maintained.

Benefits

By participating in this study, participants may experience direct benefits from family-centered care for early childhood obesity prevention. Their participation may help researchers and Geisinger develop ways to improve the care of pediatric patients. Although individual study participants will not benefit, we believe the minimal risks they face by participating are reasonable give the potential benefit future patients may receive related to pediatric obesity prevention.

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APPENDIX:

Appendix A. Family Nutrition and Physical Activity (FNPA Risk Assessment)

Family Meals	Never/ Almost Never	Sometimes	Often	Very Often/ Always
1. How often does your child eat breakfast, either at home or at school?	1	2	3	4
2. How often does your child eat at least one meal a day with at least one other family member?	1	2	3	4
Family Eating Practices	Never/ Almost Never	Sometimes	Often	Very Often/ Always
3. How often does your child eat while watching TV? [Includes meals or snacks]	1	2	3	4
4. How often does your family eat "fast food?"	1	2	3	4
Food Choices	Never/ Almost Never	Sometimes	Often	Very Often/ Always
5. How often does your family use packaged "ready--to--eat" foods? [Includes purchased frozen or on--the--shelf entrees, often designed to be microwaved]	1	2	3	4
6. How often does your child eat fruits and vegetables at meals or snacks? [Not including juice]	1	2	3	4
Beverage Choices	Never/ Almost Never	Sometimes	Often	Very Often/ Always
7. How often does your child drink soda pop or sweetened beverages? [Includes regular or diet soda pop, Kool--Aid, Sunny--D, Capri Sun, fruit or vegetable juice, caffeinated energy drinks (Monster/Red Bull), Powerade/Gatorade, etc.]	1	2	3	4
8. How often does your child drink low--fat milk for meals or snacks? [Includes 1% or skim dairy, flavored, soy, almond, etc.]	1	2	3	4
Restriction/Reward	Never/ Almost Never	Sometimes	Often	Very Often/ Always
9. How often does your family monitor the amount of candy, chips, and cookies your child eats?	1	2	3	4
10. How often does your family use candy, ice cream or other foods as a reward for good behavior?	1	2	3	4
Screen Time	Never/ Almost Never	Sometimes	Often	Very Often/ Always

11. How often does your child have less than 2 hours of "screen time" in a day? [Includes TV, computer, game system, or any mobile device with visual screens]	1	2	3	4
12. How often does your family monitor the amount of "screen time" your child has?	1	2	3	4
Healthy Environment	Never/ Almost Never	Sometimes	Often	Very Often/ Always
13. How often does your child engage in screen time in his/her bedroom?	1	2	3	4
14. How often does your family provide opportunities for physical activity?	1	2	3	4
Family Activity	Never/ Almost Never	Sometimes	Often	Very Often/ Always
15. How often does your family encourage your child to be physically active?	1	2	3	4
16. How often does your child do physical activities with at least one other family member?	1	2	3	4
Child Activity	Never/ Almost Never	Sometimes	Often	Very Often/ Always
17. How often does your child do something physically active when he/she has free time?	1	2	3	4
18. How often does your child participate in organized sports or physical activities with a coach or leader?	1	2	3	4
Family Schedule/Sleep Routine	Never/ Almost Never	Sometimes	Often	Very Often/ Always
19. How often does your child follow a regular routine for your child's bedtime?	1	2	3	4
20. How often does your child get enough sleep at night?	1	2	3	4

Scoring the FNPA

A number of the items on the FNPA are reverse scored with "Very Often/Always" being the less desirable options, so care should be taken when calculating a total score. Additional resources can be found at myfnpa.org and eatright.org.

Items to be Reverse Scored (Construct):

3 Family Eating Practices
4 Family Eating Practices
5 Food Choices
7 Beverage Choices
10 Restriction/Reward

13 Healthy Environment

Appendix B. Outcomes Table

We will measure secondary outcomes and potential mediators and moderators of the intervention models' relative effectiveness on obesity including multi-level factors in the community, clinic, and home settings as well as individual-level factors. Factors that will be assessed at the various levels are detailed below brief descriptions and citations indicating psychometric properties of identified measures. Outcomes that are particularly meaningful to patients are identified in green, PCPs in purple, and health care administrators in blue. The total number of items that parents will be asked to respond to vary by data collection time (Telephone survey= 14 items; Baseline= 156 items; 6-month= 79 items; Follow-up= 97 items). PCPs will be asked 56 items at Baseline; 12-month follow-up= 47 items; 24-month maintenance= 47 items. Health Coaches will be asked 53 items at baseline; 12-month follow-up = 44 items; 24-month maintenance = 44 items.

Table 4. Secondary Outcomes, Covariates, Mediating and Moderating Factors on Intervention Effectiveness by Level

Level and Factor	*Timing*	*Items*	*Respondent and Source*
COMMUNITY*			
1. Community Socioeconomic Deprivation[27] (Moderator) Contextual measure derived from a factor analysis of six indicators previously associated with obesity trajectories among children in the Geisinger catchment area	BL	n/a	US Census, American Community Survey
2. Rurality (Moderator) Density of persons per square mile within counties and communities where clinics are located, and participants reside	BL	n/a	US Census
3. Parent perception of neighborhood (Moderator) Food access, availability, and quality[135,136] and neighborhood pleasantness and physical activity availability[28,137]	BL	14	P-SQ
CLINIC			
4. Organizational Climate [138-140] (Moderator) Shared meaning PCPs attach to PRO measures and the behaviors they see rewarded, supported and expected, specifically related to workflow and relational climate.	BL FU 24 mo.	3	PCP-SQ, EHR
HOME			
5. Household Food Security[141] (Secondary Outcome) USDA Food Security Scale short form, which has been validated with diverse populations	BL FU	6	P-SQ
6. WIC, SNAP, HeadStart participation (Covariate) Current enrollment in US food and nutrition education programs	BL	1	P-TS
7. Demographics (Moderator) Household income, access to reliable automobile	BL	2	P-TS
INDIVIDUAL-PRIMARY CARE PROVIDER-HEALTH COACH			
8. Demographics[142,143] (Covariate) Factors that may be associated with provider adoption and effectiveness of intervention components, including specialty, training, experience, biological sex, race/ethnicity, age, self-reported height and weight status	BL	9	PCP-SQ
9. Attitudes, Norms, Perceived Behavioral Control and Intention about Obesity Prevention Intervention[79] (Mediator) Consistent with the Theory of Planned Behavior, PCPs' attitudes, perception of social norms, and perceived behavioral	BL FU 24 mo.	36	PCP-SQ

control regarding one's ability to modify FNPA risk factors will predict behavioral intentions and behavioral intentions will predict extent to which PCPs engage in the intervention			
10. Self-efficacy in Preventive Counseling for Obesity[142,143] (Mediator) Training in and self-efficacy of providing obesity-related prevention and treatment (adapt for pediatrics)	BL FU 24 mo.	8	PCP-SQ
INDIVIDUAL-PARENT/CAREGIVER			
11. Perceived Involvement in Care[144] (Secondary Outcome) Scale measures parent perception of involvement in clinical encounter (adapt for WCV)	BL (pre or post WCV), FU	20	P-SQ
12. Food Resource Management[23,92] (Secondary Outcome) Validated scales from the Cooking Matters® program assess participants' shopping behaviors and self-confidence in buying healthy foods and managing food resources	BL, 6 mo., FU	9	P-SQ
13. Demographics (Covariates) Biological sex, race/ethnicity, age, self-reported height and weight status, relationship to child, educational level, employment status	BL	11	P-TS
14. Attitudes, Norms, Perceived Behavioral Control and Intention about Obesity Prevention[78] (Mediator) Consistent with the Theory of Planned Behavior, parents' attitudes, perception of social norms, and perceived behavioral control regarding FNPA risk factors will predict behavioral intentions and behavioral intentions will predict extent to which parents engage in the intervention	BL	25	P-SQ
15. Parenting Practices[25,145] (Mediator) 5 domains of parenting practices from the Child Feeding Questionnaire: parents perceived responsibility for ensuring their child eats the right types and amounts of food (Responsibility); concern for their child's future or current weight status (Weight Concern); monitoring of their child's portions, sweet and high fat food intake (Monitoring); pressure they perceive they must put on their child to make sure he/she eats enough or finishes all the food on his/her plate (Pressure); and belief that restrictions or rewards are necessary in their child's diet (Restriction)	BL 6 mo., FU	28	P-SQ
INDIVIDUAL-CHILD			
16. Dietary Behaviors[146] (Secondary Outcome) Parent report of the average intake of fruit, vegetable, sugar-sweetened beverages	BL, 6 mo., FU	13	P-SQ
17. Physical Activity[147] (Secondary Outcome) Parent report of the average daily hours the preschool-age child was moderately to vigorously active	BL, 6 mo., FU	16	P-SQ
18. Screen Time[148,149] (Secondary Outcome) Parent report of the average daily hours the child spent watching TV, videos, and playing games on TV, computer, laptop, iPad, smartphones	BL, 6 mo., FU	4	P-SQ
19. Brief Infant Sleep Questionnare[150] (Secondary Outcome) Parent report of the average amount of daily sleep the child obtained (naps and bedtime)	BL, 6 mo., FU	9	P-SQ
20. Life Satisfaction[151] (Secondary outcome) Parent report of the child's satisfaction with life using the domain specific and general Student's Life Satisfaction Scale.	BL, FU	12	P-SQ
21. Demographics (Covariates) Biological sex, birthweight, age, race/ethnicity, baseline BMI category	BL	n/a	EHR

*Communities are defined using a mixed definition of place that incorporates minor civil divisions (boroughs, townships) and census tracts within cities. Families will be geocoded to a community based on their residential address.[152]

Timing: Baseline (**BL**): Data collected at or near enrollment. Intermediate follow-up period is at 6 months (**6 mo.**). Follow-up (**FU**) period at 12 months following baseline well child visit (allow up to 15 months for scheduling variance); and 24 months for PCPs and Health Coaches to evaluate maintenance
Items: Number of questions asked of respondent
Respondent: **P** indicates parent is respondent; **PCP** indicates primary care provider or Health Coach is respondent.
Source: Secondary data sources are identified. A telephone survey **(TS**) will be used post- consent and prior to baseline well child visit. Electronic health record (**EHR**) will be referenced at baseline well child visit and follow-up. Other variables will be collected by study questionnaire (**SQ**) following the baseline well child visit.

Appendix C. RE-AIM Elements and Planned Assessment, Indicators, and Data Sources

RE-AIM Elements *(Goal)*	Measure	Data Source
Reach *(Determine reach and representativeness of families who participate in intervention arms)*	Evaluate **participation rates** overall and by subgroups, including the percent of families who consent to each study arm; complete study follow-up; complete PRO measure (Arms 2 and 3); select FNPA topics for discussion with PCP (Arms 2 and 3); and accept referral to Food Care (Arm 3)	Study Records, EHR
	Evaluate **representativeness of participating families** by comparing characteristics (e.g., child BMI, age, sex, insurance status; parent age and sex; household food security status, rurality) of participants (i.e., those who consent, complete study follow-up, complete PRO measure, select FNPA topics, or attend Food Care) and non-participants	EHR, Parent telephone survey, Study Records
Effectiveness *(Evaluate intervention arms' impacts on health behaviors and outcomes)*	Determine **effectiveness** of intervention arms on primary and secondary outcomes	See Outcomes*
	Determine **robustness** of effectiveness across subgroups (provider type [e.g., MD, DO, CRNP, PA-C], household food security status and rurality, parent weight status, child baseline weight status, biological sex and race/ethnicity)	See Outcomes*
	Compare **attrition** by treatment arms and across subgroups	Study Records
Adoption – Providers *(Discern whether interventions will translate to new health care settings)*	Determine **rate at which providers adopted intervention** arms, including the proportion of WCV in which family-centered preventive counseling is documented, by provider; and the proportion of WCV in which PRO measure is utilized, by provider	EHR
	Evaluate **representativeness of providers** by comparing provider characteristics (e.g., provider type, age, sex, BMI) associated with higher and lower levels of adoption of intervention components (i.e., family-centered preventive counseling, PRO measure utilization)	PCP-Study Questionnaire, Study Records, EHR
	Compare characteristics of PCPs who participate in the study versus those who are unwilling/unable to participate	Non-Participant Survey
Implementation *(Identify implementation barriers; explain reasons for intervention effectiveness, or lack thereof)*	Determine fidelity to intervention delivery, including percent of eligible participants referred to Food Care (Arm 3); percent of families referred to Food Care that receive Food Care intervention (Arm 3); proportion of participants that attend in-person or virtual grocery store tour and calls (Arm 3)	Study Records, EHR
	Report implementation characteristics such as the time needed for PCP training, intervention delivery, the staffing requirements, iPad availability and programming, and information technology programming requirements, anthropometric measurement techniques (assessed by observation)	Study Records
	Identify whether PCP or parent intent to discuss obesity prevention and related attitudes, norms, and self-efficacy explain intervention implementation.	See Outcomes*
	Identify implementation strengths and barriers, including PCP self-reported barriers to implementing obesity prevention counseling; parents self-reported barriers to attending Food Care	PCP Study Questionnaire, Food Care Program Records
Maintenance *(Report sustainability of intervention components over time)*	Evaluate adoption over time, including adaptations made to FNPA and Food Care (Cooking Matters, Parent Training Program) to improve sustainability; re-evaluate adoption measures 12 months after baseline intervention contact	EHR, Food Care Program Records
	Evaluate PRO measure completion rates 12 months after final intervention contact to determine family participation following the study period; proportion of patients that return to the same clinic for their 1-year follow-up WCV	EHR
	Evaluate commitment of health system, clinic leadership, and community partner to ongoing implementation of intervention components	Stakeholder discussions

*See Appendix B. Outcomes Table