Greenlight Plus Study: A Randomized Study of Approaches to Early Childhood Obesity Prevention

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Study Protocol

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Approved by Vanderbilt University Medical Center's IRB on 5/14/2019, IRB #190311. Vanderbilt University Medical Center's IRB served as the Single IRB for this trial.

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Protocol Approval Date:

The study protocol was originally approved by the Steering Committee and DSMB on 9/3/2019.

Any amendments are detailed at the end of the protocol.

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1. EXECUTIVE SUMMARY

Greenlight PLUS is a randomized controlled trial to compare the effectiveness of two different approaches to early childhood obesity prevention in children 0-2 years of age. We will randomize 900-925 parent-infant dyads, recruited from six newborn nurseries/ primary care clinics. The participating organizations are part of both CORNET, a national practice-based research network of pediatric residency primary care practices supported by the Academic Pediatric Association (APA), and PCORnet, the national research network supported by PCORI. Parent-child pairs will be recruited in the newborn nursery or pediatric primary care clinic within the first 21 days of life. After signing informed consent, parent-child pairs will be randomly assigned to one of two study arms: In Arm 1 ("Greenlight"), during each of the recommended well child visits from 0-24 months, pediatric residents, trained in clear health communication skills and shared goal-setting, will use the Greenlight Toolkit of low literacy, age-specific, parent education booklets to promote healthy family behaviors and obesity prevention. In Arm 2 ("Greenlight Plus"), families will receive the Greenlight intervention plus a health information technology (HIT) intervention aimed at supporting family goal-setting and behavior change. This design allows us to determine if HIT and the asynchronous support it provides between well-child visits can promote additional behavior change and obesity prevention.

2. SPECIFIC AIMS AND OBJECTIVES FOR MAIN TRIAL

This research includes one primary and three secondary specific aims.

Primary Aim

Aim 1: Compare the effectiveness of the 2 arms on weight-for-length and other weight measures through age 2.

Hypothesis 1: Arm 2 will be significantly better than Arm 1 in supporting healthy child weight-for-length trajectory over 2 years.

Secondary Aims

Aim 2: Compare the effectiveness of the two approaches on parent-reported outcomes, including child feeding and physical activity behaviors, parent feeding beliefs and behaviors, media use, and quality of doctor-parent communication.

Hypothesis 2: Arm 2 will be significantly better at improving parent-reported health behaviors.

Aim 3: Examine differences in main outcomes by social determinants, including race/ethnicity, language, health literacy.

Hypothesis 3: A literacy- and culturally-sensitive approach to obesity prevention will result in equal subgroup improvements.

Aim 4: To compare weight-for-length trajectory over 2 years in both intervention arms with a non-enrolled comparison group, using data from the PCORnet Common Data Model at participating sites.

Hypothesis 4: PCORnet analysis will reveal the benefit of both Greenlight approaches (Arms 1 and 2) compared to before Greenlight intervention implementation and the added benefit of Arm 2 (Greenlight Plus) over other approaches.

2.1 COVID-19 Supplemental Aims

To rapidly respond to the COVID-19 pandemic, the study team received additional funding to conduct a mixed-methods enhancement of the PCORI-funded Greenlight Plus Study. The goal of this study enhancement is: 1) to describe the impact of the COVID-19 pandemic on social drivers of health and 2) to examine the resultant effect of the COVID-19 pandemic on infant growth in a multi-site sample of low income and minority families. This enhancement will provide data on the nature and extent of the social consequences of the COVID pandemic, with a specific focus on early childhood growth and vulnerable populations.

The COVID-19 pandemic has led to an unprecedented number of unemployment claims, increased food and housing insecurity, reduced access to health care and social support programs, a rise in stress and mental health issues, and a higher risk of domestic violence and child abuse.[1-3] We know these social drivers of health, particularly during the critical periods of pregnancy, infancy, and early childhood, can have a profound impact on long term health.[4] Because this is an unprecedented global event, we lack evidence regarding the specific stressors caused by the COVID-19 pandemic and how they will impact child health outcomes. Developing intervention strategies to support families hardest hit by the social consequences of COVID-19 requires understanding barriers that families are facing and the resources they need to address those barriers in real time. In addition, tracking the lasting consequences of this pandemic from a life course perspective will facilitate intervention strategies to support child growth and development.

Using this cohort, and taking advantage of a natural experiment, **we will address the following aims:**

Specific Aim 1: To explore the impact of the COVID-19 pandemic on changes in families' social, emotional, financial, psychological, and healthcare needs by conducting a qualitative study involving repeated interviews among parents who experienced the pandemic at various stages of their infant's life, including "early pandemic" (infant born prior to 3/11/2020), "peak pandemic" (infant born 3/11/2020 – 6/11/2020), and "later pandemic" (infant born after 6/11/2020).

Specific Aim 2: To conduct a natural experiment birth-cohort analysis in a multi-site sample of 900-925 families to describe how the timing of the COVID pandemic in relationship to a child's birth (pre-pregnancy, during pregnancy, early infancy) is associated with 1) rapid infant weight gain over the first 6 months of life, 2) parent behaviors related to child feeding and activity, and 3) psychosocial outcomes (e.g., parent depression, financial hardship, food insecurity, etc.).

3. BACKGROUND AND RATIONALE

Obesity prevention is a public health priority, and early childhood is a critical period for preventing obesity-related morbidity and reducing health disparities

across the life course. More than 20% of preschool children are overweight and 11% are obese,[5] and these rates are typically higher among children in low-income and minority communities.[6,7] Rapid weight gain in the first 12 months of life is associated with increased risk of later obesity and obesity-related comorbidities, with a disproportionate impact on low-income and ethnic minority groups.[8-12] Children who are overweight by age 24 months are five times more likely than non-obese children to become overweight or obese adolescents[8,13-15] and adults.[16,17] Overweight children and adolescents are at significantly increased risk for premature development of adult chronic illnesses[18-21] such as hypertension,[22,23] type 2 diabetes,[24,25] steatohepatitis,[26,27] and orthopedic problems.[28] Addressing obesity during early childhood requires a family-centered approach that engages children's caregivers, especially their parents.[29-32] Early childhood risk factors for later obesity include potentially modifiable factors such as giving formula over breastfeeding, inappropriate bottle use, introduction of solid foods before 4 months of age, and sugar-sweetened beverage/juice intake.[33-35] Our research group has found that "obesogenic" behaviors start as early as 2 months in high risk populations[36] (see Research Team section).

The US Surgeon General has identified health literacy as "one of the largest contributors to our nation's epidemic of overweight and obesity."[37] Over 25% of parents have low health literacy skills.[38] Low literacy and numeracy skills have been independently associated with poorer understanding of health information and worse health behaviors and clinical outcomes.[39-50] Our research group has demonstrated that low parent health literacy is associated with less breastfeeding, problems mixing formula correctly, pressuring feeding, difficulty understanding food labels, portion sizes, and growth charts, decreased physical activity, and more screen time.[43,51-58] Few clinical trials have addressed obesity prevention in the first years of life, or have examined the effect of interventions that integrate a literacy-sensitive approach or the use of HIT.[8,51,54,59-64]

The original Greenlight Intervention. The initial efficacy trial of the Greenlight intervention was funded by NIH and applied evidence-based health literacy and health communication approaches to support clinician counseling and promote family engagement to prevent childhood obesity in children 2-24 months of age. The study successfully recruited and followed 865 English- and Spanish-speaking families and over 400 pediatric resident physicians in a cluster randomized trial. The study found improvements at 24 months at one site, but not the other, and this lack of improvement at 24 months was thought to be due to: 1) suboptimal engagement between 0-2 months (pre-intervention) and 18-24 months (no well child checks), and 2) lack of family support outside the clinical setting. The proposed study will evaluate the scalability/effectiveness of a more robust Greenlight program that includes additional clinical toolkit support starting at the first newborn visit and leverages technology to provide asynchronous support outside the clinical setting particularly at 18-24 months of life with children's changing feeding patterns. Prior studies across diverse populations have demonstrated the value of digital health platforms to improve patient/family behavior change.[65-69]

4. SIGNIFICANCE

Greenlight is a primary care-based program, whose innovative health literacy-informed approach to obesity prevention is specifically designed to decrease disparities in child obesity beginning in infancy. Health literacy mediates racial/ethnic- and income-associated health disparities.[70-72] A 2008 IOM Workshop emphasized the importance of addressing health literacy to reduce health disparities.[73] Parents of infants with low health literacy have lower rates of breastfeeding, and higher rates of obesogenic behaviors including pressuring feeding, decreased activity, and greater screen time.[74] Greenlight targets these behaviors by engaging at-risk families in the newborn period, empowering parents to make informed decisions about the care of their children.

The primary care setting where pediatric residency training takes place presents an ideal setting to prevent child obesity and address caregiver health literacy using a family-centered approach.[75,76] Pediatric residency continuity clinics serve the health needs of 20% of the nation's low-income families[77] - the same communities that are at highest risk for low health literacy and child obesity. Many pediatric residents have had only minimal training in health communication skills during medical school[78] and this training typically has not focused on the importance of health literacy,[79] despite American College of Graduate Medical Education requirements for structured opportunities in health communication-related competencies.[80] Many pediatric residents begin their training with low self-efficacy for counseling, and community-based physicians continue to report low self-efficacy in these domains.[78,81,82] Improving physician self-efficacy for family counseling may lead to improved caregiver self-efficacy for behavior change, as seen for physical activity,[83] smoking,[84] and growth/nutrition.[85] These findings highlight the importance of engaging both parents and child health providers as key stakeholders in reducing disparities in early child obesity.

Using low-cost digital health technology to deliver anticipatory guidance can support early life obesity prevention in primary care. Almost all Americans own a mobile phone and 77% have smartphones; texting has ~90% penetration, with 81% texting daily.[86-88] Digital health approaches for obesity prevention may be especially beneficial for racial/ethnic minorities, who have both higher rates of obesity and high mobile technology ownership rates, including high rates of texting.[88,89] These approaches allow us to reach affected populations outside the clinic setting, with highly personalized content at low cost.[90] This proposal builds on over a decade of research by our team demonstrating that we can provide effective behavioral and chronic disease management strategies to medically vulnerable low literacy patients with obesity, diabetes and hypertension through mobile technologies (e.g., web, text messages, interactive voice response phone calls).[91-95] This work extends beyond simply sending tips or reminders via texts; an algorithmic assessment of risk behaviors, readiness for change, and self-efficacy is conducted, and tailored behavior change goals are prescribed, with prompt tracking of goals and immediate tailored feedback. Our interventions have led to improved clinical and behavioral outcomes, including reduced blood pressure, reduced sodium intake, and increases in physical activity;[93] patients have high rates of tracking engagement.[92,94] Further, our systems are fully automated, operational, and have been tested in obesity management trials conducted in primary care as an adjunct to routine clinical practice.

This proposal has multiple interested stakeholders**.** The outcomes to be measured are of high interest and importance to multiple stakeholder groups, including parents and child health providers, as well as health insurers and policy makers interested in reducing economic and ethnic disparities in child obesity. All stakeholders share common goals: a desire to prevent childhood obesity and identify /implement the most effective interventions. Parents are concerned about child obesity, the potential long-term health consequences of obesity, and how it can be best prevented and treated.[96-99] Physicians and other providers are also concerned about child obesity and want information about effective prevention/treatment.[100,101] The Greenlight Plus study will yield valuable information about which obesity prevention approach is most effective, and about family and provider experiences.

Both the proposed primary care toolkit and digital health component can be readily disseminated. The Greenlight Toolkit, as a brief educational intervention that can be embedded into existing well-child visits, has high potential for dissemination into clinical settings. The toolkit provides a standardized framework for physicians to deliver key educational messages at well visits in a clear, engaging, effective manner, and could be successfully adopted into clinical practice, using models from other pediatric well-visit-based programs such as Reach Out and Read, which now serves >4 million children across >6,000 primary-care practices.[102] The HIT component has high potential for widespread adoption due to its low cost, feasibility of utilization, and impact on behavior seen with similar health IT interventions.[103,104]

5. STUDY POPULATION AND ELIGIBILITY

5.1. Eligibility Criteria

For this study, eligible caregiver/infant dyads will be those with:

1) an English- or Spanish-speaking parent/legal guardian,
2) infant born in the newborn nursery with plans to have care in the local clinic OR presenting in that clinic for the first newborn visit (1-21 days of life),
3) attendance at first newborn clinic visit (1-21 days of life),
4) no plans to leave the clinic within 2 years,
5) completion of baseline data collection (survey data, child height and length measures prior to randomization), and
6) own a smartphone with access to data services.

Eligible physicians will include any pediatric health care provider (resident, nurse practitioner, physician assistant, or faculty physician) who provides preventive care for children in one of the study clinics. We will primarily enroll patients who are seen by residents but allow for flexibility of each local clinic site's practice patterns, which may allow for non-resident physicians to occasionally provide routine preventive care for patients primarily followed in the resident-based clinic.

5.2. Exclusions

Infant exclusion criteria:

1. born prior to 34 weeks gestation or birth weight <1500 grams; weight <3rd %tile at enrollment (World Health Organization growth curves);[105] or
2. any chronic medical problem that may affect weight gain (e.g., metabolic disease, uncorrected congenital heart disease, renal disease, high-calorie formula; cleft palate; Down syndrome).

Caregiver exclusion criteria include:

1. <18 years old;
2. serious mental or neurologic illness that impairs ability to consent/participate;
3. poor visual acuity (corrected vision worse than 20/50 with Rosenbaum Screener);
4. biological mother is HIV-positive

Multiple Gestations:

If a child is a twin, only one of the twins will be randomly selected and will be eligible for the study. If the child is a triplet, quadruplet, or other multiple gestation, none of the children from that family will be eligible.

5.3. Withdrawal Criteria

Parent-child pairs can withdraw their consent to participate at any time. Additionally, children can be withdrawn from the study at any time based on the discretion of the steering committee (which consists of the Co-Principal Investigators). Children will be evaluated for withdrawal from the study if they meet criteria for failure to thrive, based on a dropping of more than two centiles in weight-for-length based on WHO Growth curves over a 6-month period or if the child is diagnosed with a medical condition after randomization that would make them ineligible. Decisions to withdraw participants from the study will be decided by the steering committee, and the process will be overseen by the DSMB.

5.4 Additional Eligibility Criteria for the COVID-specific Aims

There are no additional eligibility criteria or exclusion criteria for participation in the COVID-related aspects of the study. Any parent-child pair enrolled in the parent Greenlight Plus study is eligible for the COVID-related aspects of the study.

6. RECRUITMENT AND RETENTION

The Table below outlines our anticipated recruitment and retention. We will employ a multi-pronged approach to recruitment and retention, including 1) use of bilingual research assistants trained in interpersonal communication, 2) recruitment through newborn nurseries and primary care clinics where children are typically brought for regular care in the first 2 years of life to receive vaccinations and other well care, 3) use of “tangible tools” as incentives and to promote engagement, 4) monetary incentive, 5) use of reminders, newsletters, holiday cards, and other materials to promote engagement.

1. Estimated number of potentially eligible study participants	5950 families; 541 residents
2. Total number of study participants expected to be screened:	2410 families; 541residents
3. Total number of study participants expected to be eligible of those screened:	1846 families 531residents
4. Target sample size:	900 families; 463 residents
5. Total number of practices or centers that will enroll participants:	6 centers
6. Estimated percentage of participant dropout:	20%

We anticipate recruitment rates will vary slightly across all six participating sites (UNC, Duke, Miami, NYU, Vanderbilt University Medical Center and Stanford). We will aim for equal recruitment at each site (150/site) but anticipate a range of enrolled participants at each site (between 50-400/site) to achieve the overall study recruitment goal of 900-925 families.

6.1. Recruitment Tracking

Participant tracking databases will be reviewed monthly by the study’s steering committee. If we note greater than anticipated attrition, the steering committee along with the recruitment and retention subcommittee, will discuss additional strategies. We will also ask participants and community liaisons for their suggestions as the study progresses.

6.2. Recruitment of Minorities

The Pediatric Primary Care Clinics included in the trial provide care for a diverse range of families, including many racial and ethnic minorities, and families with lower socioeconomic status. These 6 sites serve a clinic population that typically includes >70 % of patients on WIC and/or Medicaid, >30% of families report Spanish as their primary language, >30% African American, <40% White, and >15% self-report other racial or

ethnic minorities. In general, residents are >60% female and self-reported as >60% white, >10% African American, >10% Hispanic.

Our study team's recruiters, data collectors, interventionists and retention specialists also include members of minority populations representative of our study's target population, including the ability for Spanish-English bilingual communication. Publicity and program (intervention and control) materials will be adapted for cultural relevance, fluency, and appeal, including flyers at sites and in languages preferred by minority populations.

6.3. Procedures for Obtaining Informed Consent

Healthcare providers

As a pragmatic clinical trial, all healthcare providers in the house office continuity clinics that will be implementing the intervention will receive training in the materials, as a part of continuing education, and congruent with resident training priorities for the ACGME. Informed Consent will be obtained from healthcare providers (primarily resident physicians) for their participation in surveys, focus groups or key informant interviews.

Parent-Infant Pairs

Potential study participants will be invited by staff or research assistants at either the newborn nursery or Pediatric Primary Care Clinic to participate in the research during regularly scheduled appointments, and/or will be exposed to posters in the clinic announcing the study. Caregivers will be assured that their care at the clinic will not be affected by their willingness to participate or actual participation in this research. If interested, caregivers will be referred to the local Research Assistant for possible enrollment. Local Research Assistants will then provide informed consent. The local Research Assistants will be trained in the Ethical Conduct of Human Research and HIPAA regulations and will be approved for performing study recruitment by the IRB. Consent forms will be designed at the 6th grade level and will be read to potential caregiver participants and discussed in an interactive manner to confirm caregiver understanding of the risks and benefits of study participation. A copy of the signed consent form will be provided to the caregiver. Spanish translation and Spanish materials will be used for Spanish speaking families. Children will be <2 years of age and will not directly participate in the study consent process, and assents to participate are not feasible or suggested at this age. If families meet inclusion/exclusion criteria, they will then be asked to confirm their interest in participation and will complete baseline data collection. Caregivers will be informed that they may leave the study at any time without repercussion. We will use visual aids and enhanced low-literacy communication strategies to ensure adequate understanding of the study prior to obtaining informed consent. Immediately following in-person baseline data collection (before randomization), caregivers will receive an automated text prompt to ensure that they can receive messages from the platform, and research assistants will assist them to save the number in their phone as the Greenlight Plus Study.

6.4. Randomization Procedures

Randomization Strata:
Randomization will occur centrally (at Vanderbilt) at the level of the individual child-caregiver dyad. After consent is obtained each dyad will be randomized to treatment Arm 1 or 2. We will use randomly permuted block sizes between two and four to ensure balance. Randomization will be conducted using the REDCap randomization tool (www.project-redcap.org), providing real-time randomization stratified by blocks on participant characteristics (preferred language and Newest Vital Sign score stratified into score of ≤2,>2, or missing). Participants will be randomized after completion and quality checks of baseline data collection after the first study visit.

Random Assignment: Each potential dyad's contact information, including child age and dominant language use, will be loaded into the secure recruitment database upon identification as a potential participant and assigned a unique study identification number (dyad id). The recruitment database will follow each potential dyad from the point of identification through eligibility assessment and enrollment through disqualification or randomization. The recruitment database will track all eligibility and enrollment criteria and include a utility that checks still-eligible study candidates for criteria that must be met prior to randomization. Upon identifying dyads who have met all of these criteria, research staff will engage a database utility that performs randomization by identifying the stratum into which each potential dyad should be randomized, and populating the next available slot in the appropriate randomization schedule with the dyad's id. The database user will not be able to see, and will be unlikely to anticipate, the arm assignment (treatment versus control) for each dyad, especially when multiple dyads within a stratum are randomized at once. Once the dyad is assigned to an arm, a link is established between family id and arm assignment (Greenlight Arm vs. Greenlight Plus Arm). This link will not be writable by any study staff and will be viewable by the study statistician in the randomization schedules.

Randomization Data Management: The link between dyad id and arm assignment will be stored in the randomization schedule, to which only the statistician will have read access. All randomized dyads will remain in the recruitment database for the duration of the study so that recruitment and enrollment reports can be generated on demand by all study staff. Study staff will be blinded to the dyad's arm assignment as this can be hidden in the REDCap database.

All dyads' ids will be exported into a measurement database along with the fields necessary to conduct timely data collection and on-demand reporting by any study staff. Arm assignment will not be exported to the measurement database. As such, it will not be possible for measurement staff to know a dyad's arm assignment based on the information available in the measurement database.

In addition, once randomized, the dyad ids (both treatment and control) will be exported into an intervention database along with the fields necessary to conduct the treatment and control procedures and allow on-demand reporting. Arm assignment will not be

exported to the intervention database. Intervention staff (in both the control and treatment conditions) will likely know which dyads have been assigned to which arm. This knowledge is unavoidable and redundant with knowledge that will be apparent from contact with the dyads within each arm.

Randomization Data Safety: All databases (recruitment, measurement, etc.), will be stored within a password protected shared drive within the university computer system. All study staff will have access to the databases upon submitting the required password. The randomization schedule will not be stored in the intervention database making it impossible to access in this manner.

6.5. Techniques for Retention

We strive to achieve an 80% retention rate with our recruitment and retention strategies outlined above. Our retention plan includes:

1) developing positive reciprocal relationships between study staff and participants.
2) developing a clear protocol that outlines the collection of contact information, systematic contacts, financial incentives, tangible tools, and a participant tracking database;
3) utilizing other methods of staying in contact with participants, such as utilizing the Prompt platform and text messaging through Twilio to re-engage participants from both arms of the study, and taking advantage of social media applications like Facebook.
4) accessing participant contact information from the Electronic Health Record if contact is lost.
5) obtaining primary outcome data (weight and length) from a participant's new health provider if the participant changes clinics during the study. We will ask permission from the participant to do this during the consent process.

Retention Specialist: As one retention method, all participants will receive a dedicated mobile telephone number to contact the study team. A staff member will be dedicated to monitoring this phone number and tracking all information and question reported by participants. Additionally, the Greenlight Plus team will collect multiple contact numbers and the contact numbers of others who may help us re-establish contact with participants.

Incentives: As a thank you for being in the study, we will give participants a gift card right after we do the survey at the times shown on the chart below.

Time Point for Getting Data	Amount Participants Will Get	About How Long the Survey Will Take
T1 (First Visit)	$20.00	45-60 minutes
T2 (2-weeks)		5-10 minutes
T3 (1 month)		5-10 minutes
T4 (2-months)		10-15 minutes
T5 (4-months)		5-10 minutes
T6 (6-months)	$20.00	20-30minutes
T7 (9-months)		10-15 minutes
T8 (12-months)	$20.00	20-30 minutes
T9 (15-months)		5-10 minutes
T10 (18-months)	$20.00	5-10 minutes
T11 (24-months)	$20.00	45-60 minutes

Participants will also receive $20 for completing the final study visit, where the primary outcome of 24-month weight and length were collected.

Additional Retention Strategies:
To support families who could not attend their child's 24-month child well-child check, the study team offered to mail the family a scale and tape measure to obtain the final weight/length measures (noted in the study database as self-collected). When possible, families took a photo of the measurement and uploaded via secure link to the REDCap database. A study team member was available via phone or secure teleconference (e.g., ZOOM) to provide support.

Finally, the Greenlight Plus team hopes that both the intervention and control content themselves will create an experience that leaves participants wanting to come back for more through hands-on, practical, and meaningful topics.

6.6. Incentives for participation in COVID-related study
Participating families will receive a $50 incentive for each key informant interview (maximum of $150). Participants will also receive an additional $20 as a one-time incentive for the new COVID-19 related survey measures added to the study.

7. INTERVENTION

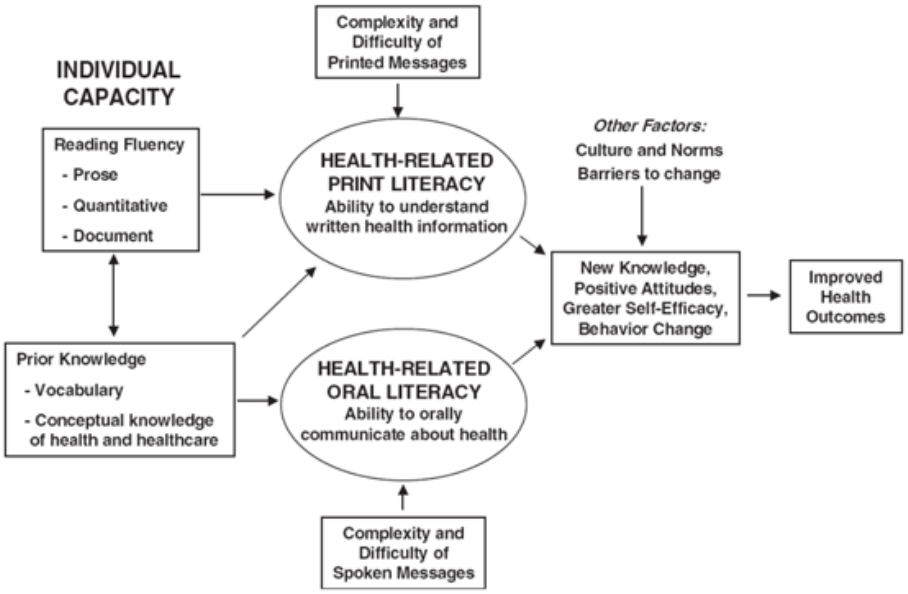
7.1. Conceptual Framework
Social Cognitive Theory (SCT), with a focus on caregiver health literacy skills, serves as the conceptual framework for designing and implementing the intervention.[106] According to SCT, behavior is determined by environmental factors (such as modeling, family/peer influences, social support, social norms) and cognitive factors (such as self-efficacy, self- concept). Individuals are more likely to engage in behaviors they see modeled or rewarded, as well as those for which their engagement receives direct

reinforcement. Thus, a key component of interventions for young children is to involve parents in modeling health-promoting behaviors to children in the earliest years. Self-efficacy to engage in particular behaviors, such as feeding behaviors or increased family physical activity,[107] is also integral to this model. This model also acknowledges the role of affective factors (such as parental depression) as they may influence behavior. Recent developments of intervention approaches based on SCT include applying motivational interviewing to health promotion.[108]

The central role of health literacy in health behavior change is a cornerstone of this intervention. Factors contributing to health literacy and the potential impact of health literacy on direct and indirect health effects have been well elucidated by Rootman,[109] members of the Institute of Medicine (IOM) Committee on Health Literacy, and others.[73] The proposed study will focus on the interaction between the primary caregiver and his/her child's pediatric healthcare provider. David Baker, an expert in health literacy, suggested the conceptual model (see Figure 7.1) about the relationship between individual capacities, health literacy and health outcomes.[110]

As suggested by the IOM report and other related literature reviews, low literacy-adapted interventions should include the following elements: (1) reducing the complexity of health information;[111-117] (2) improving the communication skills of health providers (e.g., using "teach back," effective use of printed materials)[45,118-122] and (3) easing navigation of the healthcare environment (e.g., patient navigators, improved access to existing resources). In creating our Greenlight educational materials, we used Doaks' Suitability Assessment of Materials framework.[111] Low-literacy principles used included: plain language text (4th to 6th-grade reading level, short sentences), suitable white space, as well as behavior-oriented, meaningful and actionable visual images (e.g., photographs or diagrams of foods, portion sizes, or physical activities appropriate to each developmental stage). A traffic-light motif is used throughout to further reinforce key messages: green sections = positive health behaviors to adopt; yellow sections = behaviors to be adopted rarely or with caution; red sections = behaviors to avoid. Low-literacy "tangible" tools include portion size snack cups and place mats promoting appropriate portion sizes and balance. Health care provider training facilitate the use of the Toolkit (i.e., reinforcing messages by circling, drawing or writing) and provider skills acquisition with respect to use of "teach back" (having parents say in their own words what they understand) and effective goal-setting (use of "SMART" goals (specific, measurable, attainable, relevant, timely)). For patients randomized to Greenlight Plus, the digital health component will reinforce the messages of the Greenlight Toolkit's goal setting while integrating principles of SCT, clear communication, and health literacy.

Figure 7.1 Conceptual framework[110]



7.2. Description of the Intervention

Pediatric healthcare providers at all of the participating clinics will receive training in (1) health communication skills (health literacy, shared goal setting, cross-cultural communication), and (2) use of the Greenlight Toolkit (English and Spanish low-literacy toolkits used with families during 0-24 month well-child visits), facilitating parent education and engaging parents in shared goal-setting for health behavior change.[123] Toolkits address key issues to prevent childhood obesity at each well child visit. Arm 1 will provide the standard Greenlight Intervention, Arm 2 will add the HIT component, where families will be given access to a web/mobile self-management support site that our team has built to provide educational components of the Greenlight toolkit and will provide virtual coaching messages and opportunities for families to set/monitor goals for health behavior change.[124,125]

Arm 1: *Greenlight:* As noted above, informed by social cognitive theory (SCT)[106,111-113,115,126-128] and health literacy principles, the Greenlight Intervention was designed to be administered by pediatric healthcare providers at each well-child visit from 0 to 18 months. The Intervention has two main parts: (1) a low-literacy toolkit for parents, including booklets and developmentally-tailored tangible tools reinforcing recommended behaviors at each well-child visit; and (2) a health communication curriculum for child health providers, with modules on teach-back and shared goal-setting. Applying SCT to child obesity prevention, parents are more likely to adopt a new health behavior that satisfies four criteria: 1) the behavior is directly reinforced (motivation), 2) the behavior is modeled repeatedly (social cues), 3) parent expects the new behavior will produce real benefit (outcome expectancy); and 4) parent is confident in her/his ability to perform the behavior (self-efficacy). The Greenlight intervention was designed to satisfy these SCT criteria. At each well-child visit: a trained physician provides information to help the parent make a causal link between the parent behavior and a healthy child (outcome expectancy), and a Toolkit offers visual models of recommended behaviors (social

cues), and shared goal-setting around short-term behavior change (self-efficacy). Each Toolkit was designed to be easily shared with other family members at home.

Toolkit: Core Booklet and Tangible Tools: At each well-child visit, the physician presents the parent with a developmentally appropriate "Core Booklet," and has the option to further reinforce messages with one of six Topic Supplements (breastfeeding, formula feeding, infant sleep, TV and other screen time, family physical activity, family nutrition). Each Core Booklet is tailored to the child's developmental stage and corresponds to one of the routine well-child visits between birth and 18 months. To promote shared goal setting at each visit, the back page of each Core Booklet provides blank lines to allow for tailored goal-setting, as well as a check-box list to help guide families to make specific goals. Each Core Booklet introduces or reinforces three age-appropriate parent behaviors thought to be most strongly associated with preventing obesity during early childhood based on peer-reviewed literature.[22,106,111,113,114,126,127,129,130]

Topics include: breastfeeding promotion, avoidance of sugary drinks, attention to satiety cues, promotion of healthy food choices, appropriate portion sizes, reduction in screen time, and activity promotion. Each of these behaviors is highlighted on the cover of each Core booklet within a green "traffic light". We will review the booklets annually and update as needed to reflect any new guidelines that are published during the course of the study. At four of the well-child visits during study participation, the parent-child dyad will also receive a "Tangible Tool," which is intended to promote intervention fidelity and reinforce Core Messages.

Revising the curriculum: Because this study will take several years to implement, it is possible that new evidence will become available that changes anticipatory guidance recommendations or best-practices for childhood obesity prevention. Each year the steering committee will evaluate the available literature to determine if updates to the training materials, intervention toolkit (i.e., booklets) or health information technology messaging is required. These changes will be documented in the study protocol.

Physician Training Curriculum: Physicians will receive training on principles of effective health communication and how to use the Greenlight Toolkit. As a pragmatic trial, there will be several opportunities and modalities for resident physicians to receive training, including in-person lectures and online training modules. Every 6 months after the initial training, booster trainings are offered in person or by video-enabled webcast. Trainings support current ACGME requirements for resident training and are easily integrated into the resident education curriculum during noon-conferences, ambulatory morning report, or pre-clinic conference with support from the local residency programs.

Applying the principles of active learning,[131-133] the Training Curriculum uses obesity prevention content to teach physician-parent communication skills in three domains: (1) clear health communication techniques (e.g., plain language, "teach back" technique, and the effective use of printed materials);[45,118-122] (2) cultural and linguistic competence (e.g., family structure, community resources, and language interpreters);[132] and (3)

shared goal setting.[133] Complementing the Toolkit's content, the physician training curriculum promotes conversational dialogue with minimal jargon, reference to the Toolkit's images, and frequent verbal verification of understanding of information (e.g., "teach back"). In addition to interpersonal communication, the curriculum addressed learner-centered content in each of the six competencies espoused by the ACGME: medical knowledge (evidence-based behaviors associated with early childhood risk of obesity); patient care (incorporating anticipatory guidance into a routine preventive care visit); professionalism (respecting cultural differences in infant feeding practices); systems-based practice (curriculum that acknowledges obesity as a public health problem); and practice-based knowledge (integration of the Greenlight intervention into daily practice).

ARM 2: *Greenlight Plus:* Families randomized to the Greenlight Plus arm will receive the Greenlight Toolkit (identical to Arm 1) *PLUS* a HIT intervention starting at the newborn clinic visit. Prior to randomization, all families will receive basic instructions on how to interact with the text-messaging application (with occasional text messaging used as a retention tool in the control group). After randomization, families in Arm 2 will receive basic instructions on how to access the Greenlight technology platform, which includes the iOTA text-messaging application and a website dashboard (usable on desktop or mobile platform).

The core of the HIT intervention is a text-messaging application, based on the interactive Obesity Treatment Approach (iOTA). iOTA was originally designed for adult patients to induce an energy deficit sufficient to produce weight loss through the modification of routine obesogenic lifestyle behaviors. iOTA was created in response to: 1) the frequent finding of poorer weight loss outcomes and less intervention engagement among underserved, minority populations,[134] and 2) the difficulty in translating traditional intervention approaches (e.g., in-person counseling, strict calorie/physical activity targets) to the community health center setting. These traditional approaches are cognitively complex, require considerable literacy/numeracy skills, and make inherent assumptions about participants' ability to access healthful resources. In contrast, iOTA is straightforward and does not require expert knowledge or expensive resources. iOTA's adaptive design is prime for self-management of behavioral goals for parents of infants and toddlers. Behind the scenes, the iOTA system is sophisticated, but uses low-cost, easy-to disseminate digital health software systems. It relies on a series of interconnected algorithms and content libraries. An algorithm tailors feedback, selecting content from a vast content library. From our skills training library, we send materials to assist behavior change efforts.

From the participant perspective, the experience using the intervention platform is simple. Parents take a short 10-minute survey asking about their behaviors and readiness for change (e.g., a parent of a 12- month-old would be asked: "How many ounces of juice do you usually give each day?" If more than 4 ounces per day, readiness and self-efficacy for reducing juice is assessed.) Based on responses, the system will immediately assign 1 personally-tailored behavior change goals for the care of their child (e.g., no juice, weaning from the bottle) to work on for 2 weeks. Every 2

weeks, participants will work on a new goal for novelty and to cover all domains associated with early life obesity prevention (e.g., sleep, eating, activity). Participants self-monitor their adherence to these goals via text messages sent 3 times per week. In these texts, participants also receive immediate tailored feedback based on their current adherence and long-term progress.

Based on self-monitoring data, we will send motivational messages to support participants' behavior change efforts. For each family, personalized "dashboards" will be maintained on the Greenlight website; parents will be able to easily access their dashboard using the link texted to them via the iOTA system or with their unique ID number. The dashboard will aggregate all activity on the platform site and content the participant has been texted via iOTA. Participants will be able to access Greenlight toolkit booklets and activities and track their child's goals and growth. Data from the iOTA platform will be pulled into each participant's dashboard by connecting directly to the iOTA platform. The participant dashboard will be built optimized for desktop, tablet, and smartphone display.

7.3. Process Measures

Process measures will include: training completion rates of pediatric healthcare providers, parent-child attendance at well-child visits collected via attendance logs; data collection process collected via timed logs and identification of any issues that arise during the data collection procedures; retention barriers and facilitators via call logs conducted by the study retention specialist; and parent-child satisfaction with study participation. Data will also be available on frequency of use and interaction with the iOTA text messaging platform, including: the number of texts expected and actually sent; the number of texts received and undelivered; the number of participants that responded within the response window; participant self-ratings on goal progress; number of free texts (texts that do not conform to the expected format) sent by participants; number of iOTA surveys sent and number completed; and individual-level distribution of non-response to texts during each block and over time. Each of these process data elements, with the exception of participant self-reported goal progress, will be unblinded throughout the study to facilitate effective implementation.

8. MEASUREMENTS

Study data will be obtained at enrollment and at each well visit by parent interview and chart abstraction. Interviews will be conducted by trained, bilingual research assistants in English or Spanish, based on the caregiver's language of preference. Participants will have the option at the 24-month timepoint to complete surveys self-administered online. Throughout the study, investigators at each study site will conduct periodic review and observation to ensure reliable data collection.

8.1 Key Outcomes

The study's primary outcome is Weight For Length (WFL) trajectory from baseline to 24 months. Secondary outcomes include: 1) child BMI z-score trajectory, 2) child WFL z-score trajectory from baseline to 24 months (by WHO standards), and 3) the percent of

children who are overweight and/or obese at 24-month follow-up. We will collect additional data on parent-reported behaviors, and though they will not serve as secondary outcomes per se, they will be included in the analysis plan a priori as pre-specified behavioral variables to potentially explain mechanisms by which the intervention may or may not impact the primary or secondary outcomes. These include 1) parental report of breastmilk feeding at 6 months; 2) parental report of timing of introduction of solids; 3) parental report of juice/sugary drink consumption at 6, 12, and 24 months; 4) parental report of child diet composition at 24 months; 5) parental report of child media use at 9, 15, and 24 months; 6) parental assessment of communication quality at visits at 12 and 24 months(CAT);[135,136] and, 7) parental feeding beliefs and behaviors at 6 months.[137,138] Weight and length measurements will be collected at baseline and at each study visit by trained clinic staff based on HHS guidelines for accurate measurement.[139] For participants who change clinics throughout the study, we will accept medical records released from their new clinics as well as self-reported measurements from participants if the measurement comes from a measurement taken at the clinic. We will examine WFL and BMI z-scores based on WHO tables for children 0-2, and percent of children overweight at age 2 using CDC criteria.[140]

Family Reported Outcome Measures. Parent-reported indicators of infant feeding and physical activity behaviors will include: (1) child and family activities (e.g., sweet beverages, “tummy time”, screen time) and (2) parent self-efficacy. Survey items are derived from previously validated measures of infant feeding behaviors, infant and toddler media use, and other early childhood health behaviors. Reports of infant feeding style will be derived from the Infant Feeding Style Questionnaire (IFSQ)[137] which has been validated for Latino populations.[141] When necessary, additional items to assess intervention-targeted behaviors have been adapted from existing behavioral scales. The primary caregiver’s satisfaction and perception of physician communication will be assessed after select visits using the Patient Communication Assessment Tool (CAT).[135]

In Aim 4 we will also examine historical and concurrent anthropomorphic data of children age 0-2 years seen at each clinic site via the PCORnet Common Data Model (CDM).

Pediatric Resident Reported Measures: Annually we will measure resident knowledge, communication practices, and satisfaction with the Greenlight program. We have adapted surveys developed and published by our research team.[101,142]

Greenlight website data: Study investigators will be able to use google analytics to track use of the participant dashboard.

Table 8.3: Questionnaire Measures

Item	Item Burden (Minutes)	Newborn (0 months)	2 Weeks	1 Month	2 Months	4 Months	6 Months	9 Months	12 Months	15 Months	18 Months	24 Months
Time frame for collection of measures		**0-14 days**	**4-20 days**	**21-45 days**	**46-90 days**	**91-150 days**	**151-225 days**	**226-318 days**	**319-407 days**	**408-495 days**	**496-635 days**	**636-820 days (*preferred window 716-744, window extension up to 912 days for COVID delays)**
Primary Outcome Measures												
Child Weight and Length		X	X	X	X	X	X	X	X	X	X	X
Items Necessary to Address Specific Aims												
Parent and Child Demographics	6 min	X										
Follow-Up Demographics (Change in address, number of people living in home, language of survey administration)	1 min	X	X	X	X	X	X	X	X	X	X	X
Household Food Insecurity (USDA 6-Item version)	1 min	X							X			X
Health Literacy												
Newest Vital Sign (NVS)	2 min	X										
PHLAT-8	6 min					X						
Child Diet Measures (Infant Feeding Practices)	3 min	X	X	X	X	X	X	X	X			
Child Diet Measure (CDC Short Dietary Questionnaire)	8 min									X	X	X
Patient Communication Assessment Tool (CAT)	6 min	X							X			X
Communication Extra (additional questions about satisfaction with provider and Greenlight materials over 2 years)	1 min											X
Child Media Exposure	2 min				X			X		X		X
Additional Items of Interest												
Weight Perception	1 min							X	X			X

Caregiver Feeding Practices												
BEBQ	4 min				x							
IFSQ	12 min						x					
IFSQ-Parenting Behaviors Subset	3 min								x			
CFQ	4 min											x
Child Physical Activity Measures (Tummy Time and Unrestricted Floor Time)	1 min				x	x	x					
Outdoor Playtime Recall	1 min											x
Child Sleep Practices												
BISQ	2 min						x					
CSHQ-23	6 min											
Additional Sleep Items	1 min			x	x	x		x	x	x	x	
Parent Self-Efficacy (PSOC-5)	1 min	x										
Place-Based Survey	4 min	x							x			x
Employment Status/Commute Time	1 min	x					x		x		x	
Financial Hardship Items	1 min	x							x			x
Maternal Depression (PHQ-9)	3 min	x					x		x			x
Parent Diet	2 min	x							x			x
Parent Physical Activity	1 min								x			x
Parent Health Status (diabetes, HRN, HLD)	2 min	x										
Maternal Pre-Pregnancy BMI	1 min	x										
Maternal Gestational Weight Gain	1 min	x										
Childcare Measure (1 item)	1 min				x		x		x			x
Parent Social Support (ENRICHD)	2 min	x										x
WIC	1 min	x	x	x	x	x	x	x	x	x	x	x
Parent Acculturation (BASH)	3 min	x										
Child Cup Use	2 min							x	x	x	x	x
Home Internet Access	2 min									x		
Parent Media Use	2 min								x			
Parent-Child Technoference	3 min									x		
Everyday Discrimination	3 min											x
COVID-19 Supplement Items												

		COVID Baseline	2 Weeks	1 Month	2 Months	4 Months	6 Months	9 Months	12 Months	15 Months	18 Months	24 Months
Coronavirus Impact Scale		X			X	X	X	X	X	X	X	
COVID-19 Exposure and Family Impact Survey (CEFIS)		X										
Duke COVID-19 Survey		X										
Family Assessment Device – General Functioning Scale		X										
FRAS Subscale		X										X
Self-Efficacy		X										
Total Burden at Timepoint		**41 min**	**5 min**	**6 min**	**14 min**	**13 min**	**23 min**	**10 min**	**34 min**	**20 min**	**14 min**	**43-44 (57-58) min**

*During the newborn period, we obtained 2 child weight and length measurements: birth and baseline. Birth weight and length was collected from the newborn nursey. These measurements would be taken at the time of birth *if available*, however if they were not collected at the time of birth, we included measurements up to 48 hours after birth as long as the measurements were still collected in the newborn nursery. Baseline weight and length measurements were from the clinic visit closest to participant enrollment in the study and within the timepoint timeframe.

8.2. Quality Control

While it was the original intent of the study to conduct quality control measures on 10% of study measures, COVID safety protocols made this infeasible.

Fidelity measures will be asked by data collectors at each data collection time point to participants, as feasible, with a minimum of 10% of visits assessed:

1. Did you receive a "Greenlight booklet" during your child's visit today?
2. Did you and your doctor discuss any specific pages in the booklet during the visit?
3. Did you and your doctor use the Greenlight booklet to set any goals today?

8.3 Measures related to the COVID-specific aims

First, we will conduct a qualitative evaluation of social needs facing low-income families and the degree to which current social supports are adequate to address those needs. Trained interviewers will conduct 1:1 interviews with the primary parent in English or Spanish. They will follow an interview guide grounded in the social ecological model to explore the social and behavioral impacts of COVID19 (Appendix 1). These interviews will occur three times, during July-September 2020, December 2020-February 2021, and April 2021-June 2021. Participants already enrolled in the parent study will be eligible to participate. Recruitment for the qualitative study will occur during previously scheduled data collection visits (i.e., well-child checks) for the parent study.

Second, we will conduct a birth-cohort analysis by engaging the participants who were recruited prior to the pandemic onset (N=117) and those that will be recruited over the next 9 months (N=783, for total N=900). We will add survey measures that are informed by theory (e.g., newly developed coronavirus impact scale, measures of family resilience, etc.)[143,144] and the qualitative interviews in Aim 1. All newly proposed measures will be obtained at a COVID baseline and the 24-month follow-up. The Coronavirus impact scale will be collected at all additional timepoints beginning at 2 months.

COVID-19 Related Measures (Newly developed, obtained from NIH repository)	
Coronavirus Impact Scale	Measures COVID-19 impacts including changes to daily routines, family income, access to healthcare, access to social supports, family discord, etc. (12 items).
COVID-19 exposure and family impact survey (CEFIS)	Measures COVID-19 stress across multiple domains including number of affected family members, degree of social isolation, and effects of parenting, financial hardship, access to food/medication, etc. (37 items)
Duke COVID-19 Survey (Stress/Anxiety due to COVID-19)	Measures changes in sleep, anxiety, depressive symptoms. (9 items)
Family Assessment Device	General Functioning Sub-Scale. (12 items)[146]
FRAS Subscale	Measures utilization of social and economic resources (11 items)

COVID-19 Related Self-Efficacy	Measures self-efficacy to respond to the psychological and social challenges of the pandemic. (10 items)

9. PARTICIPANT SAFETY AND ADVERSE EVENTS MONITORING

9.1. Potential Risks and Protection against Risks

Human Subjects Involvement and Characteristics: At each academic medical center (Vanderbilt, U Miami, UNC, NYU, Stanford, and Duke), between 100-200 caregiver-child dyads will be recruited over approximately 12-15 months (total N=900-925). Caregiver-child dyads will be recruited by a trained local Research Assistant in the newborn nursery or at the first well-child visit at the local Pediatric Resident Primary Care Clinic and will be followed until the child's 2 year well child care visit. The pediatric residents at each academic medical center who participate in the Pediatric Resident Primary Care Clinic will also be recruited (up to 110 pediatric residents per year over 4 years at each medical center). In addition, other healthcare providers (nurse practitioners, physician assistants, faculty physicians) will be recruited, as local practice variations may allow for non-resident physicians to occasionally provide care for patients primarily followed in a resident-based clinic.

Full inclusion and exclusion criteria for the recruitment of caregiver-child dyads is outlined in the **Research Section**.

This study will target caregivers and their young children. Targeting children this young is deemed necessary to optimally intervene and improve family lifestyles to prevent childhood obesity. Starting at this young age is imperative to promote healthy behaviors during this critical period in which lifelong diet and physical activity behaviors are formed.

Protection Against Risk: Study personnel will comply with all federal, state, and local laws. Particular attention is drawn to the Food and Drug Administration Regulations for human subject research (45 CFR 46), children as a vulnerable population (45 CFR 46 Subpart D), and the International Conference on Harmonization (ICH) Guidelines for Good Clinical Practices (Guidance for Industry E6).

We will be administering the PHQ-9, which includes a question about self-harm to caregivers as part of the participant survey. If a caregiver reports severe symptoms of depression (PHQ-9 score of 20 or higher) or endorses the 9th item on the PHQ-9, indicating thoughts of self-harm, we will enact the following depression protocol. A notification in the REDCap database will alert the RA/member of the research team administering the survey, who will give the caregiver the resources handout, which includes crisis hotline numbers and mental health services, and follow existing site-specific clinic processes to alert the local clinical team in real time. The site PI (or the clinic social worker, if available) will follow up with the caregiver within 48 hours to discuss and will refer her to the ER or crisis hotline if needed.

IRB approval: Any additional protocol, informed consent documents, and all types of volunteer educational information will be submitted to all the IRB for review and must be approved before the study is initiated. Any amendments to the protocol must also be approved by the IRB prior to implementing any changes in the study. We will also keep the IRB informed of any significant adverse events.

Adverse Events: Although adverse events are not anticipated from the nature of this study, all volunteers will be under the care of experienced providers and the policy of the 6 participating Academic Medical Centers is to provide all necessary care to volunteers who experience an adverse event during a study. The investigator or designate is responsible for the detection and documentation of adverse events (AE) and serious adverse events (SAE) in persons participating in this study. At each clinical evaluation and safety evaluation during the study period, the investigator or site personnel will document any AEs or SAEs, as detailed in this protocol. A telephone number will be provided to caregivers who will be asked to immediately report any adverse events. Adverse events (ER visits, and hospitalizations) and any concerns from participants will formally be assessed monthly by the local site Co-PIs. If a subject concern is reported, the local PI will consult with Dr. Rothman (Contact PI) to assess severity and determine if the event is related to participation in the study. If the study intervention is implicated in the adverse event the caregiver and their child will be removed from the study and notifications of appropriate authorities will occur.

Safety Monitoring Oversight: The Data Safety and Monitoring Board (DSMB) in conjunction with the Steering Committee at each Academic Medical Center will oversee the safety of volunteers participating in the study as needed. The PI at each site will be responsible for timely identification of adverse events and will report them to the chair of the DSMB and IRB if they occur.

Compliance with Protocol: Each investigator must adhere to the protocol as detailed in this document. Each investigator will be responsible for enrolling only those volunteers who have met study eligibility criteria. A physician may implement a deviation from, or a change in, the protocol to eliminate immediate hazard(s) to trial subjects without prior DSMB and/ or IRB approval. As soon as possible, the implemented deviation or change, the reasons for it and if appropriate, the proposed protocol amendment(s) must be submitted: 1) To the IRB for review and approval/favorable decision, 2) To DSMB for agreement; and if required, and 3) To the regulatory authority(ies). Any protocol violations must be reported to the DSMB in a timely manner. Protocol violations that result in an adverse event must be reported on an AE/SAE form and on the protocol violation form. A written report should be sent to the DSMB as soon as possible. The report should include: 1) Nature of the error, 2) Standard reporting information (patient's clinical status before and after the event), 3) Steps taken to review the error, and 4) Steps taken to assure the error will not occur again. Protocol violations must also be reported to the IRB. Protocol deviations, which are departures from the protocol for which the staff has no control (e.g. subject misses a study visit for a given day), should be documented in the study record and the DSMB is not required to be notified of these protocol deviations.

Confidentiality: The results of the research study may be published, but study participant names or identities will not be revealed without express written consent of the study participant. Records will remain confidential. To maintain confidentiality, the principal investigators will keep records in locked cabinets and results of tests will be coded to prevent association with study participant names. Study participant records will be available to the study staff, and the local participating Academic Medical Center IRB. Data will be collected during this study and stored with code numbers as the only identifiers. Surveys completed by study participants will not contain any identifying information and will also be entered into a comprehensive data collection database (REDCap). REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. All data will be maintained in password access databases behind a secure firewall. In addition, all communication between our iOTA software's application programming interface (API) and third-party software is encrypted using SSL, and information on Greenlight website participant dashboards will not contain identifying information.

9.2. Potential Benefits

Potential benefits to the caregiver and their child for participating in this study include: (1) improved knowledge and health behaviors related to healthy child behaviors (2) reduction in the development of overweight in the child at age 2, and (3) improved use of clinical and preventive services. There is no guarantee of benefit to the volunteer from this study. Participants will also obtain modest financial compensation for their time and receive items that reinforce healthy behaviors ("tangible tools"). As outlined above, the risks to the volunteers of this study are reasonable in light of the potential benefits. Potential benefits to Pediatric Healthcare providers who participate in the study include: (1) improved health communication skills (intervention arm), and (2) improved knowledge and training in promotion of health lifestyles and obesity prevention. As outlined above, the risks to the volunteers of this study are reasonable in light of the potential benefits.

Potential Risks: This is a low-risk study. The main risk would be loss of confidentiality if a study database were compromised.

9.3. Safety Monitoring Plan

The following section outlines the respective action responsibilities of different study parties:

Responsible Person Activities

Local Principal Investigator

1. Evaluate adverse events for severity, causal relationship to study intervention, and action taken and outcome.
2. Promptly report all severe adverse events (SAEs) and unexpected events to DSMB, and IRB.
3. Notify the DSMB and IRB of any new safety information.
4. Provide written response to DSMB and IRB action plans if required.

5. Provide meeting minutes and adverse event reports to DSMB.
6. Respond to any recommendations from the DSMB.
7. Evaluate study components and content for appropriateness, report adverse events associated with these components to the Contact PI.
8. Evaluate screening data for clinically relevant depression, caregiver contact, and appropriate referral to community resources for support and treatment.
9. Notify IRB of recommendations to modify or suspend studies.

Local Research Assistant

10. Complete the IRB Adverse Event Report for each event.
11. Provide local Principal Investigator appropriate documentation for review and recommendations.

DSMB

12. Ensure that the protocol has specified guidelines regarding the identification and procedures for the reporting of adverse events.
13. Review summary reports and tabulations of adverse events.
14. Recommend continuation, modification, suspension of clinical studies based on clinical significance of events.
15. Maintain written records of all communication, assessments and recommendations as well as all materials reviewed.
16. Ensure review process is free from conflicts of interest.

9.4. Informed Consent Documents

Please see Appendix 2 for the current informed consent documents.

10. BLINDING

10.1 Introduction

In all clinical trials, the potential for bias is one of the main concerns. Bias arises from conscious or subconscious factors and can occur from the initial design through study conduct, data management, data analysis and interpretation. A general approach to avoid biases is to keep the participants and the investigators blinded to the identity of the assigned arms until all data points are collected.

Guiding principle #1: All Greenlight Plus personnel that are in a position to change the study protocol or its implementation in study participants should be blinded to information that may allow them to do so, from when the study starts until the study ends, with specific exceptions as delineated in this document.

- This means that all investigators and study staff that have the potential to impact the study's outcome, except as outlined below should be blinded to study data aggregated by study arm.

Guiding principle #2: The study statistician and programmers s/he designates will be unblinded to post-randomization outcome, mediator, moderator and process data for the purposes of generating DSMB reports.

- The study statistician will remain objective when carrying out the activities of conducting the trials – preparing randomization schemes, randomizing individual subjects, processing of the data, cleaning and editing the data, preparation of analyses/reports of outcome, mediator, moderator and blinded process data, and transmitting those data to the DSMB.

10.2 Clarification of Terms

- The "study starts" at a site when the first participant signs informed consent (i.e., resident physician prior to training).
- The "study ends" when the outcomes (primary and secondary) have been collected on all participants at the final data collection timepoint.
- Outcome variables – primary and secondary outcomes as described in the study protocol
- Process variables – e.g. training, recruitment, intervention implementation, fidelity, adherence, retention/attrition

10.3 Blinding of Investigators by Data Type

All data collected will be categorized *a priori* into one of 6 categories:

i. **Demographic information**: including age, sex, country of origin, and contact information is not blinded, either at the individual level or aggregated by arm.

ii. **Study arm assignment** is concealed until the time of randomization. To the extent possible (as described below), staff responsible for collecting outcome data will be blinded to study arm assignment after randomization occurs.

iii. **Post-randomization outcome, mediator and moderator data:** all personnel are blinded to outcome, mediator and moderator data, aggregated by arm, except for the study statistician and DSMB.

iv. **Post-randomization, individual level process data:** these variables will be specified a priori and noted in the study protocol, or clearly identified in an amendment to the study protocol. They may be viewed Principal Investigators throughout the study and may also be shared with the interventionists, Project Coordinator, Co-investigators, or Managers. Arm-level process data may be viewed by the Principal Investigators and shared with the interventionists, Project Coordinator, Co-investigators or Managers.

v. **Post-randomization, blinded process data:** investigators and study staff will be blinded to these, aggregated by arm, with the exception of the Statistician, programmers they designate, and the DSMB.

vi. **Safety data** are collected for the purpose of insuring participant safety. These will be made available to principal investigators throughout the study. They will be aggregated by study arm.

10.4 Summary of Blinding by Personnel Type

The study arms are, BY DESIGN, not able to be totally blinded. However, some blinding can be maintained. Measurement staff should not be informed of the intervention that individual participants are receiving and should have **no role** in the delivery of the intervention. Efforts should be made to avoid participant (child/parents) interactions that result in open chatting with assessors about the interventions they have

received. Measurement staff should be trained to end any such communication when initiated by participants.

Specifically, we will take steps to blind the study staff (e.g., research assistants) to family study status to the greatest extent possible. For example, we will collect baseline measures before randomization. If feasible, study staff will collect follow-up measures without knowing the study assignment of a family. If feasible we will collect measures related to mobile platform use through electronic surveys that do not require study staff engagement. HOWEVER, it may not be feasible to truly blind the study staff to family study status – if: 1) study staff need to help provide technical support for the use of IOTA/Greenlight Platform, and/or 2) study staff need to ask questions face-to-face to families (and possibly residents/clinicians) about their engagement with the technology intervention. Despite these limitations, we will make all reasonable efforts to maintain blinding of outcome assessors, especially those responsible for measuring height and weight data (the primary outcome).

Investigators/staff are blinded as to arm of an **individual** participant	**NOT POSSIBLE**
Individual child and/or parent participants are blinded as to the intervention they are receiving	**NOT POSSIBLE**
Main outcome assessors are blinded as to the intervention the **individual** participant is receiving	**YES (to the extent possible, see above)**
Investigators and all study staff, except statisticians/analysts, are blinded as to ALL OMM and blinded process data aggregated by arm	**YES**
Site staff are unblinded to the aggregated by arm process measures identified *a priori* or by amendment to the protocol as unblinded	**YES**

10.5 Unblinded Process Data

There may be specific process data collected in one or more arms that the Principal Investigator and study staff want to review aggregated by arm before the end of the study. Those variables will be declared *a priori*. Those variables will include:

- Number of texts messages sent, received, and expected
- Number of text message responses (to goal setting and follow-up)
- Number of intervention surveys sent and number of responses
- Number of website access and clicks in website
- Attendance at Clinic Visits

Should sites wish to examine additional blinded process variables aggregated by arm, after the study has begun, those requests would be approved by the steering committee and the DSMB, and those variables will be clearly listed as unblinded variables in an amendment to the study protocol.

10.6 Interim Analysis: Not Planned

In Greenlight Plus, there will be no planned interim analysis of the primary outcome and so only the study or independent statisticians/analysts preparing and presenting the analysis to the DSMB, as well as the DSMB, are unblinded.

Interim analyses may be performed on measures/data that are collected after randomization providing they are 1) not the primary outcome or analyses and 2) they do not require adjustment by study status (resulting in unblinding).

10.7 Communication of the Policy for Blinding

To ensure that this policy is clearly understood and communicated, all Greenlight Plus study principal investigators and study staff will affirm the statement below. This can be completed by email to the lead study coordinator. Over the course of the study as new personnel are hired, they will also confirm compliance.

11. STUDY DESIGN, STATISTICAL CONSIDERATION AND ANALYSIS PLAN

11.1 Analysis Plan

We will examine baseline characteristics of the two treatment arms using percentiles for continuous variables and percentages for categorical variables. The primary outcome is child weight for length (WFL) trajectory and secondary outcomes include: WFL Z-score, BMI Z-score, and the percent of children with overweight and/or obesity at 24 months. We will conduct *intent to treat* analyses *that* compare *the growth trajectories for children in the Greenlight Plus and Greenlight arms over the two years of follow-up.* We choose, as our primary outcome, WFL as opposed to Z-score or percentile because raw values have properties that are superior to standardized outcomes when conducting longitudinal growth modeling,[147] particularly when variables included in standardizations are included in regression models. Recent literature has highlighted problems with BMI-Z score (and other standardized BMI outcomes) for measuring extreme obesity (i.e., BMI percentiles >99%), especially in intervention contexts.[148] While the literature often reports Z-scores, we only include them as a secondary outcome because we believe their limitations outweigh their benefits. We chose WFL as opposed to BMI as our primary outcome since, for children age 0-2, the CDC recommends basing standards on WFL over BMI.

For primary and quantitative secondary outcome analyses, we will test the overall treatment effect (i.e., the combined treatment main effect and the treatment by age minus one month interaction) with a two-sided 0.05 significance level. To account for within-patient and within-site correlation, we will use linear mixed effects models .[149] From these models, we will estimate non-linear intervention effects across the age range (one through 24 months) using restricted cubic splines. Though the study will be randomized, eliminating the potential for confounding, we will control for baseline precision variables believed to be associated with outcomes, including, birth weight, gender, race and ethnicity, caregiver health literacy, caregiver's primary language, annual household income, food insecurity, and years of education. For the analysis of

overweight and/or obesity at 24 months, we will fit a longitudinal logistic regression model and summarize the results at the 24-month age to estimate and test for the intervention effect.

Missing data: For missing independent variable data we will use multiple imputation with 100 imputation datasets generated using predictive mean matching. We will conduct analyses on all datasets and will combine results using Rubin's Rule.[150] We will not impute missing outcome data for analyses as such imputation does not add information to the model unless auxiliary data are included.

Additional behavioral outcomes can be classified into distinct categories: binary (infant feeding style), ordinal (infant and caregiver feeding style, self-efficacy), and continuous / skewed continuous (physical activity, perception of communication). The behavioral outcomes will be analyzed longitudinally and cross-sectionally at the time they were observed. We will use logistic regression analyses for the binary outcome variables and proportional odds cumulative logistic regression for the ordinal and highly skewed-continuous outcomes. For other continuous outcomes, we will use linear regression analysis. For each analysis, we will provide treatment effect estimates and 95% confidence intervals and will test for evidence against the null hypothesis (of no treatment effect) using a likelihood ratio test at the two-sided 0.05 significance level. Like the primary outcome analysis, we will control for precision variables that are associated with outcomes even though they are not associated with treatment assignment, including site, gender, race and ethnicity, caregiver health literacy, caregiver primary language, annual household income, food insecurity, and years of education.

As exploratory analyses, we will evaluate heterogeneity of treatment effects based on subgroups defined by race and ethnicity, caregiver preferred language (English, Spanish), health literacy, and food insecurity by adding subgroup by treatment interactions. Interactions will allow us to estimate treatment effects within subgroups separately. We will test for treatment effect heterogeneity by testing for evidence against the null hypothesis that treatment effects are homogenous at the two-sided 0.05 significance level.

We will also compare the participants in the current trial to an external cohort of children not enrolled in the current Greenlight Plus Study (GPS). At each site, the standard Greenlight (GL) Intervention will be administered to those randomized to it and to those who did not participate in the study. We will collect additional data that includes: 1) children who were not exposed to the present Greenlight Plus Study interventions because they were born in the years preceding GPS, and 2) children who were exposed to the Greenlight intervention because they received care during the GPS study time but were not enrolled in GPS.

Power calculations: We conducted simulation-based calculations to estimate the power for the primary outcome. We generated the Greenlight and Greenlight Plus data using linear mixed models of observed data in the original Greenlight study. From these

model parameter estimates we generated child growth in simulated Arms of the study. We calibrated treatment effect sizes by assuming, due to randomization, outcome values between the two treatment arms were equal at study initiation, but children in the Greenlight Plus arm gain weight more slowly than in the Greenlight arm and in such a way that 24-month outcomes differ by a fraction of standard deviation in 24 month WFL. Let SD be the standard deviation in each outcome at month 24 (this is calculated based on original study estimates of the random intercept variance, random slope variance, and measurement error variance) and let ES be the effect size expressed as a fraction of SD. We generated and fit datasets 1000 times, conservatively assuming 30% attrition by the end of the study, to examine the power to detect differences in growth rates that induce a range of values for ES. We observed that we will have ample power for all outcomes if the ES is ≥0.2SD (the differences in trajectories lead to 0.2 SD differences in 24-month outcomes). The power to detect a treatment effect that is equal to 0.2SD is: 0.91 for WFL,0.94 for WFL-Z, and 0.92 for BMI-Z. Because analyses of behavioral outcomes will involve binary (logistic), ordinal (proportional odds) and continuous (linear) data regression analyses, we focus on the power to detect treatment effects in the binary data setting due to their relatively low power. We assume 15% missing data for each analysis. We report power as a function of prevalence in the Greenlight arm (pG) and the odds ratios (OR) for the Greenlight Plus arm to the Greenlight arm. We calculate at least 80% power to detect a treatment effect (assuming equal sample size per arm): 1) for pG=0.05, OR>2.20, 2) for pG=0.10, OR>1.83, 3) for pG=0.15, OR>1.69, 4) for pG=0.20, OR>1.61, 5) for pG=0.25, OR>1.56, 6) for pG=0.30, OR>1.53, 7) for pG=0.35, OR>1.51.

11.2. Site-specific Data Capture

At all major data collection time points, data are entered directly into a REDCap database. REDCap is a secure, web-based data management system that allows direct entry of participant data (e.g., measurements, responses to survey questions, etc.) into an electronic format. This direct entry system facilitates the process of downloading and transferring data to the research coordinating unit (RCU). Other REDCap features include built-in data validity checks as well as automated export procedures for downloads to Excel and common statistical packages (SPSS, SAS, Stata and R).

11.2.1. Data collection and recording

Research material obtained from human subjects will primarily involve the collection of self-reported data from surveys and questionnaires from Caregivers and Pediatric Residents. In addition, the weight and height of each child will be collected at each well-child visit. For the 24-month timepoint, a child's height and weight will be collected from another visit at the same clinic, or at another sub-specialty clinic that shares the same EHR, if a well-child visit is not available during the timepoint window. Measurements will only be used if the child comes in for a visit that would not affect their weight (e.g. ear infection). These measures would normally be collected for these visits and, as such, do not represent increased burden or risk on the child or family participating in the study. Finally, medical record review will occur during the first two years of the child's life to obtain information about the child's use of clinical services during the course of the

study. All information gathered will be recorded on paper records or directly into REDCAP and will be maintained in the REDCAP study database.

11.2.3. Database closure
During active data collection, a copy of the REDCap data will be periodically downloaded into an excel file. These files will be housed in a read-only format on a secure server. After data collection is complete, the REDCap database will be moved into inactive status, where all data are still visible but no new entry can be made.

11.2.4. Data security and confidentiality
All data collected on paper will be housed in a locked file cabinet at the offices of the research staff. Access to the files is restricted to study staff. Files will be labeled by the unique participant IDs assigned to each parent-child pair. On REDCap, all files are protected by the need for a user name and password. Through REDCap's user rights function, the data analyst can limit and grant access for specific tools to study staff as needed. Any computerized data will be kept on a secure server at Vanderbilt with limited access and/or in a read-only file. Any material that must be thrown away that involves participant information will be shredded through the document management procedures available at Vanderbilt through Cintas.

11.2.5. Data quality assurance
Many of the features of the web-based REDCap data management system, such as range checks and branching logic, are designed to ensure the quality and completeness of the study data. In addition, all data are manually entered directly into the database on-site, which eliminates data entry errors and greatly reduces the occurrence of skipped data. After every data collection session, the data analyst will review the data entered for both flagged issues noted in data collection and blank answers. These will be corrected as necessary before analysis. Anthropometric measurement error will be reduced through quality checks, which involve replicating, within a small margin of error, 10% of all measurements by another data collector.

11.3 Analysis plan for COVID-related aims
COVID Aim 1 (qualitative): All interviews will be transcribed. Transcriptions will then be coded using a hierarchical coding system by two independent reviewers. We will identify themes by a process of repeated review. Based on those themes, we will develop a schema to describe the social effects of the pandemic.

COVID Aim 2 (quantitative): To account for regional differences, we will calculate the difference between the child's date of birth and the time public health quarantine measures were instituted in each enrollment city. The primary outcome will be child growth rate over 6 months (collected as a part of the primary study). We will model the primary outcome using a linear mixed effects model, controlling for baseline demographics, study site, and intervention condition.

Finally, we will study the moderating effect of the COVID pandemic on the original intervention by including an interaction term between intervention assignment and the

timing of the pandemic as defined above. We hypothesize that for families who experience social isolation, our text-messaging based intervention may be more effective.

12. Amendments to the Study Protocol:
All amendments to the Study Protocol will be approved by the Steering Committee, DSMB, and IRB. All amendments will be appended to the study protocol with the rationale for the change and the date on which the change was implemented.

The study protocol was initially approved by the Steering Committee and DSMB on 9/3/19.

Amendment 1 (3/26/2020): IFSQ, previously planned to be administered in full at the 6-month time point, was split into two measures. The belief section and 7 behavior questions will be administered at the 6-month time point, and 11 additional behavior questions will be administered at the 12-month time point. These changes were made in the table on page 20.

Amendment 2 (8/6/2020):

1. Updated data collection table (table 8.3) to reflect changes to measures at the 9 month, 12 month, 15 month, 18 month, and 24 month data collection timepoints. New or revised measures included:
    a. New parent media surveys at 12 and 15 months, including measures of access to broadband internet, parent use of various media types, and "technoference"
    b. Revised measures of child diet practices at 24 months, to include a shortened, but validated, version of the Child Feeding Questionnaire
    c. Revised measures of child diet intake at 12 months to include the frequency with which each food type previously asked about is consumed.
    d. Added measures of parent perception of child weight at 12 months (already measured at 24 months)
    e. New measures of when a child uses bottle, sippy cup, or cup at 9 months, 12 months, 15 months, 18 months, and 24 months.
    f. A correction was made to table 8.3 to reflect that the child media survey is collected at 15 months, not 18 months.
2. Details regarding the new COVID-related aims, including updates to the following sections: 2.1, 5.4, 8.3, 6.6, and 11.3
3. A new appendix was added with the moderator guide for the key informant interviews for the COVID-specific aims. The appendices were re-numbered accordingly.

Amendment 3 (9/22/2020): In response to recruitment challenges from the COVID pandemic, eligibility criteria were expanded to allow children presenting to the newborn clinic visit up to day of life 21 to be eligible for the study. The original criteria stated that

children would be eligible if they presented up to day of life 14. This was changed in the Executive Summary (section 1) and the section on eligibility criteria (section 5.1).

Amendment 4 (2/11/2021): As recruitment by site is variable, we added language on page 10 to be able to recruit more participants at some sites to reach final recruitment goal. “We will aim for equal recruitment at each site (150/site) but anticipate a range of enrolled participants at each site (between **50-400/site**) to achieve the overall study recruitment goal of 900 families.”

Amendment 5 (7/29/2021): The total recruitment goal was amended to a range of 900-925 throughout the protocol. This allows for a buffer for any participants we have reached out to for recruitment to be given ample chance to participate in and be randomized to the study.

Amendment 6 (11/17/2021):

1. Dr. Eliana Perrin, the original Co-Principal Investigator at the Duke site, moved to Johns Hopkins but stayed on the study as a Co-Principal Investigator. A new Site Principal Investigator, Dr. Charles Wood, was added on as the Duke representative.
2. Parent exclusion criteria was edited to exclude biological mothers who are HIV positive for safety concerns as breastfeeding would not be encouraged for these families.
3. Added language clarifying that if an exclusion criterion was diagnosed post-randomization, participants would be withdrawn from the study. This was intended in the original language and was the process of the study team throughout the trial. Additional language was added to clarify this.
4. Table 8.3 was edited to reflect updated surveys collected at the 24-month timepoint. Total survey items were decreased for participant burden considerations. New or revised measures included:
    a. Added a footnote in Table 8.3 to clarify baseline weight and length measurements to easily identify where and when these were collected.
    b. Added note for preferred timeframe for data collection at the 24-month timepoint.
    c. Added Outdoor Playtime Recall measurement at 24-months.
    d. Removed CSHQ-23, Parent Self-Efficacy (PSOC-5), Employment Status/Commute Time, Parent Acculturation (BASH), Coronavirus Impact Scale, COVID-19 Exposure and Family Impact Survey (CEFIS), Duke COVID-19 Survey, Family Assessment Device – General Functioning Scale, and Self-Efficacy from the 24-month timepoint.
5. Added option for participants to complete the 24-month survey through a self-administered online REDCap survey to increase survey retention and to decrease participant burden.

Amendment 7 (4/25/2022):

1. Extended the final data collection window from 820 to 850 days allowing extra time for participants to come in for their well-child checks with COVID delays affecting scheduling (updated in table Table 8.3).
2. Added language for the 24-month timepoint to include not only a measurement from a well-child check but to also include measurements collected from another visit at the same clinic if a well-child visit is not available during the timepoint window. Measurements will only be used if the child comes in for a visit that would not affect their weight (e.g. ear infection).

Amendment 8 (8/22/2022):

1. If a participant has changed clinics, we will accept "self-reported" anthropometric measures from participants that were taken in a clinic. We have edited section 8.1 to include the clarifying sentence, "For participants who change clinics throughout the study, we will accept medical records released from their new clinics as well as self-reported measurements from participants if the measurement comes from a measurement taken at the clinic."
2. Extended the final data collection window from 850 to 912 days allowing extra time for participants to come in for their well-child checks with COVID delays affecting scheduling (updated in table Table 8.3). Priority will still be given to measurements collected in the original window, but a case-by-case acceptance of measurements collected up to day of life 912 will be considered.

Amendment 9 (10/17/22):

1. An additional incentive was added to support retention at the final timepoint. Text was added to section 6.5 of the protocol. That text reads, "Participants will also receive $20 for completing the final study visit, where the primary outcome of 24-month weight and length were collected." As some participants had already completed the study at the time of this amendment, all participants who had already completed the study were offered the additional incentive.
2. To support families who could not attend their child's 24-month child well-child check, the study team offered to mail the family a scale and tape measure to obtain the final weight/length measures (noted in the study database as self-collected). When possible, families took a photo of the measurement and uploaded via secure link to the REDCap database. A study team member was available via phone or secure teleconference (e.g., ZOOM) to provide support.

Amendment 10 (7/13/23):

1. A typo was corrected in the table detailing the timing of survey items (table 8.3) to indicate the outdoor play survey items were collected at 24-months.
2. Minor edits for clarity were made to the statistical analysis plan. In addition, food insecurity was added as a covariate to the primary model, as there is a planned HTE analysis.
3. Section 11.2.1 was updated to indicate that at the 24 month timepoint, height and length measurements might be obtained by abstracting EHR data from sub-

specialty clinic visits, not only limiting to primary care visits, with the goal of improving retention at the primary timepoint.

Amendment 11 (9/6/23):

1. Corrected typos in the protocol including:
    a. Added “University” to Johns Hopkins to site list on cover page
    b. Corrected SASH to BASH in Table 8.3 and Amendment 6 language
    c. Added “annual household” to income for clarification in Section 11.1
    d. Corrected Amendment 6 language to include “Principal” in titles

Amendment 12 (1/4/23)

1. Added some minor clarifications in the statistical analysis section, Section 11.1.
    a. Removed the phrase “likelihood ratio test.”
    b. Removed the phrase (patient nested within site) as it was redundant.
    c. Clarifies that the “baseline value of the outcome” included in the model was actually birthweight as birth length was a highly unreliable measure.
    d. Changed the phrase, “general linear mixed effects logistic regression model” to “longitudinal logistic regression” for clarity.

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