Leveraging Ongoing Home Visitation Programs to Address Obesity Disparities Among Underserved, Low-Income Mothers and Children (Obesity Health Disparities Research Center)

Study Protocol & Statistical Analysis Plan

NCT03433456

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Sponsor: NIMHD

National Clinical Trial (NCT) Identified Number: NCT03433456

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STATEMENT OF COMPLIANCE

The trial will be conducted in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and applicable United States (US) Code of Federal Regulations (CFR). The Principal Investigator will assure that no deviation from, or changes to, the protocol will take place without prior documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial subjects. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all subject materials will be submitted to the local Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any subject is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from subjects who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Leveraging Ongoing Home Visitation Programs to Address Obesity Disparities Among Underserved, Low-Income Mothers and Children (Obesity Health Disparities Research Center)
Study Description:	This two-arm, parallel, randomized controlled trial (RCT) tests the effectiveness of a simple obesity intervention (HABITS) delivered as part of ongoing home visiting services, compared to the existing home visiting services without obesity-related content on mothers' and children's obesity risks.
Objectives:	The objectives of the study are to compare the effects of treatment on children and primary caregivers' weight outcomes at 6 and 12 months, and to compare the effects of treatment on maternal feeding practices, habit strength of targeted behaviors, and features of the household environment relevant to targeted behaviors at 6 and 12 months.
Endpoints:	The primary endpoint is caregiver and child weight at 12-months
Study Population:	Participants will be 148 mothers (>50% African American; 100% low income) and their children (0–5yo at baseline) enrolled in a home visiting program in central Alabama.
Phase:	N/A
Description of Study Intervention:	The HABITS intervention focuses on habit formation and modifications of food and activity cues in the home to support habit formation. Habit formation is focused on improving five behaviors: 1) fruits/vegetables, 2) fried foods, 3) sugar-sweetened beverages, 4) physical activity and 5) self-monitoring.
Study Duration:	12-months
Subject Duration:	12-months

1.2 SCHEDULE OF ACTIVITIES (SOA)

	Baseline/Enrollment	6-months	12-months
Demographics	X		
Medical history changes		X	X
Caregiver anthropometrics (weight, height)	X	X	X
Child weight	X	X	X
Home food and activity environment (Home Food Assessment; HFA and Home Inventory Describing Eating and Activity Development; H-IDEA)	X	X	X
Habit strength (Self-Reported Habit Index; SRHI)	X	X	X
Food and Activity Frequency Survey (Modified from NHANES)	X	X	X
Personal Health Questionnaire Depression Scale (PHQ-8)	X	X	X

2 INTRODUCTION

2.1 STUDY RATIONALE

Low-income and racial/ethnic minority adults and their young children are especially at-risk of obesity,[1] and the lack of access to evidence-based obesity efforts further contributes to these disparities.[2,3] Even the most successful obesity prevention strategies have had limited success among under-resourced families, partly because effective obesity interventions are neither accessible nor tailored to address families' poverty, limited education, lack of access to healthier foods and other barriers affecting the ability of these families to adhere to lifestyle changes in real-world settings.[2,3] While conventional weight management interventions are typically comprehensive, addressing a breadth of nutrition, activity, and behavioral topics,[31-33] there are a few key behaviors (e.g., self-monitoring of weight, consistent physical activity) that have been consistently associated with long-term weight management.[4-8] As such, focusing on helping families develop healthy habits around a few key behaviors may be an effective, more efficient approach to weight management. Further, this type of simplified, targeted approach may be particularly well-suited for under-resourced, overburdened families.[9] This type of simpler, more targeted intervention focusing on the mastery of a few, simple behaviors is consistent with a habit-formation paradigm, which focuses on frequently and consistently engaging in a target behavior in response to a specific cue until that behavior becomes automatic.[9,34-38] Given that habit-formation and automaticity rely on repeated engagement in the target behavior in response to consistent contextual cues, it is necessary that such an intervention include modification of cues in the household environment, where most food is consumed among US families, in order to support the development and maintenance of targeted healthy behaviors. Thus, the proposed study is focused on implementing an obesity-prevention intervention that prioritizes the habit-formation of a few behaviors from multi-component, evidence-based obesity interventions while addressing relevant cues in the home environment to support habit-formation of targeted behaviors. The current intervention is embedded within an ongoing federally funded home visiting program, which provides an ideal infrastructure for engaging historically underserved caregivers and their children within their homes. By embedding the study intervention into an existing home visiting program, dissemination and scalability of the study intervention (if effective) is feasible.

2.2 BACKGROUND

Obesity and health-related disparities persist among socioeconomically disadvantaged adults and children. Although a nationally representative study found a decline in obesity for children ages 0-5, this was not true for economically disadvantaged children.[10] In fact, 40% of low-income children enrolled in federally-funded programs are overweight (≥85th BMI percentile) by age five, with an obesity (>95th percentile) prevalence of 16.3% among low-income 2-4yo children in Alabama.[11-14] Similarly, low-income women and those with less education are disproportionately affected by obesity.[1] Even the most successful obesity reduction/prevention strategies have had limited impact among under-resourced families, partly because effective obesity interventions are neither accessible nor tailored to address families' poverty, limited education, lack of access to healthier foods and other barriers affecting the ability of these families to adhere to lifestyle changes in real-world settings.[2,3]

Maternal behaviors and the home environment are likely key pathways of obesity risk in early childhood.[15,16] Maternal factors such as mothers' diet and feeding practices are instrumental in shaping children's health behaviors and weight outcomes.[17-21] Similarly, a variety of factors within the home environment have also been associated with healthful dietary behaviors. For instance, both household

food availability (foods present in the house) and accessibility (whether available foods are in a form or location that facilitates their consumption, such as fruit on the counter) are associated with children's dietary intake and weight status.[22-24] Since health behaviors developed in early childhood influence habits and weight trajectories across the lifecourse,[17,18,25-30] interventions are needed to address these pathways early in the child's development. These findings support our effort to explicitly tackle maternal factors as well as the home environment as key determinants of children's weight trajectories.

Simple, targeted interventions focused on habit-formation may be efficient and effective. While conventional family-based obesity interventions comprehensively address nutritional, physical activity, and behavioral topics,[31-33] only a handful of behaviors (e.g., self-monitoring of weight, consistent physical activity, regular eating patterns) have been consistently, and empirically, associated with long-term weight management.[4-8] Thus, helping individuals develop healthy habits around a few key behaviors may be as effective and more efficient for impacting energy balance and weight management than addressing a wide-ranging set of topics. A simplified approach targeting a select number of behaviors may be particularly well-suited for under-resourced settings and populations.[9] This approach is also consistent with the growing literature supporting habit-formation for weight management.[9,34-38] Habit-formation interventions focus on frequently and consistently enacting a target behavior within a certain context or in response to a specific cue until the behavior reaches automaticity.[9,34-38] Once habits are well-established (i.e., automatic), then they become less reliant on intentional control or awareness and more resistant to competing demands (e.g., mental fatigue, negative affect).[38] A handful of studies suggest that habit-formation interventions focused on select energy-balance behaviors (e.g., reducing fat, increasing daily steps, consuming low-energy dense snacks, controlling portions, decreasing intake of sugar-sweetened beverages, reducing sitting time) are feasible and result in greater weight loss than usual care when delivered in primary care[9,34,39] and are effective in improving parental feeding practices (i.e., increased provision of fruit/vegetables and healthy snacks, decreased serving of sweetened drinks) for children ages 2-6yo.[40]

Helping families modify their home environment may facilitate habit-formation. Since habit-formation and automaticity rely on the repetition of a behavior in response to consistent contextual cues, it is imperative to address the cues in the individuals' personal and household environment that are conducive to the development and maintenance of targeted healthy habits. Modification of household cues to support behavior change- such as increasing the availability of washed and cut fruits/vegetables and the visibility of cues to promote physical activity, or removing energy-dense foods from the home or storing in inaccessible locations- is grounded in the principles of "choice architecture", which posits that our environment ultimately determines the choices we make (i.e., breakfast choice is determined by breakfast options available).[41-44] Two recent trials examined the effectiveness of modifications in the participants' household environment on weight management.[45,46] Treatment resulted in significant weight loss in these predominantly White, well-educated samples, [45,46] and outcomes seemed particularly promising for women and other adults living in the household.[47] However, less is known about the utility of these household environmental modifications for addressing obesity in underserved and low-income women and their children.

The proposed study leverages an established home visiting program to deliver an in-home obesity intervention to underserved mothers and children who would otherwise not receive these services. Consistent with a capacity building approach, we aim to extend the curriculum and mission of an ongoing home visiting program to address obesity and related health disparities among low-income women and children (see also[48]). Home visiting programs are embedded in a comprehensive system of child and maternal health designed to optimize child development and prevent adverse outcomes.[49-53]

These programs are effective in improving children's physical and psychosocial health, immunization rates, breastfeeding, and overall cognitive and social development.[47,53-70] The home visiting infrastructure is ideal to address obesity among underserved mothers and children because it: (1) already engages low-income families at a critical point in the intergenerational transmission of obesity; (2) provides in-home services to address ecologically relevant cues and promote generalization to the family environment;[71,72] (3) removes many of the barriers of outpatient programs (e.g., transportation, childcare need); (4) provides services for an extended period of time to ensure mastery of skills and behaviors; and (5) is already implemented in urban and rural areas nationwide,[58,68,73,74] which would facilitate future dissemination and scalability. To date, however, there has been no comprehensive effort to address maternal-child obesity as part of these home visiting services.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

This study involves providing a health behavior intervention to low-income mothers or primary caregivers and children; therefore, the use of children as participants is inherent to the nature of this protocol. If a mother becomes pregnant during the course of the study, we decided not to exclude or discontinue her from the study, as the habit behaviors pose no risk and are likely beneficial to her as well as her unborn child but are also primarily aimed at providing healthy options for the child in the study. The study intervention, which is aimed to improve health behaviors of mothers or primary caregivers and children, is considered low-risk. Additionally, because the study assessments only involve completion of interviews, surveys, vitals, and home food assessments, there is still less than minimal risk to participants. There is a low risk of emotional or psychological discomfort from participants answering personal questions about their eating and activity behaviors. There is also a possible minimal, mild, and temporary risk for physical overexertion due to exercise from increased walking and physical activity. To protect the rights and welfare of these participants, they will be assured that their regular home *visiting* services will in no way be affected by their decision to participate, or not participate, in the study. While we are offering financial incentives to mothers or primary caregivers, these incentives are modest and are only intended to compensate for time completing assessments.

In our preliminary work providing these services, mothers or primary caregivers did not report increased burden from participating in this program. Participants receiving the obesity prevention curriculum were just as likely to meet the benchmark areas defined by Health Resources and Services Administration for evaluating the conventional home visiting program, which suggests that the additional obesity prevention content did not detract from the existing services or over-burden participants receiving the combined program. Also, participants were 27% less likely to discontinue home visiting services when they received the combined home visiting + obesity prevention curriculum as compared to those receiving the conventional program alone in our prior preliminary work.

2.3.2 KNOWN POTENTIAL BENEFITS

By targeting children and their mothers or primary caregivers, the current intervention has the potential to improve maternal behaviors and outcomes while also addressing the intergenerational transmission of obesity by testing whether maternal factors and home environment mediate children's outcomes. The intervention has the potential to reduce obesity and risk factors associated with obesity for participating mothers or primary caregivers and their children and targets a specific population that carries a disproportionate burden of obesity. This initiative represents a unique opportunity to increase access to

obesity treatment/prevention services by leveraging an ongoing home visiting infrastructure that provides family-oriented services to families most at risk for health and obesity disparities. This partnership greatly improves the potential to disseminate cost-effective and sustainable evidence-based obesity efforts on a larger scale. This 12-month intervention will provide important information about the effectiveness of this intervention delivered within the home environment of low-income families. Finally, if the program intervention is deemed successful, the program can easily be implemented in conjunction with hundreds of other similar home visiting services to reduce the impact and prevalence of obesity on low-income families and children throughout Alabama and other states.

3 STUDY DESIGN

3.1 OVERALL DESIGN

This is a cluster randomized trial in which home visitors (n=18 anticipated) employed by our partner (First Teach Home Visiting Program) will be randomly assigned to deliver the home visiting standard curriculum with or without HABITS (n=9 home visitors in each arm).

Caregivers with a child 0-5 years of age who are enrolled in the First Teacher Home Visiting program and who have completed their initial 90-day home visiting program benchmark testing will constitute our initial recruitment pool (>50% African American, 40% White, <10% other/multiple race). First Teacher Home Visiting Program enrolls caregivers with young children in their free and voluntary services through community outreach. In order to be eligible for home visiting services, families must have a social risk factor such as poverty, social isolation, lack of material and social support, lack of transportation and limited education and literacy.

Home visitors will approach their families who are potentially eligible to introduce the study, gauge interest, and screen interested families for eligibility. Designated study staff determine of families are eligible based on the completed screening form and inclusion/exclusion criteria. Home visitors are informed of family's eligibility and notify the family. Eligible families are then introduced to a blinded study assessment worker who schedules the enrollment and baseline visit.

Assessment workers (who are distinct from home visitors and masked to group assignment) will bre responsible for completing informed consent, enrolling caregiver-child dyads into the study, and completing Visit 1 (baseline), Visit 2 (6-month), and Visit 3 (12-month) assessments.

After completing Visit 1 (baseline) assessment procedures, families will be told by their home visitor which study arm they have been allocated to, for those in the HABITS intervention arm (i.e., home visiting standard curriculum with HABITS) will begin receiving the HABITS intervention at their home visits for 12-months.

3.2 END OF STUDY DEFINITION

While Primary Completion will be defined as the date of the last 12-month assessment data collection of the last participant, the End of Study will be the date that caregiver-child benchmark data and home visit completion data have been received from our home visiting program partner, as these data will provide necessary covariates for the conduct of our statistical analyses and are needed to ensure the study does not affect family services

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

Families enrolled in home visiting will be invited to participate in the study, with limited exclusion criteria. Caregiver-child dyads will be eligible to participate regardless of weight status because the targeted health behaviors are relevant and beneficial for all caregivers and children. Improvements in maternal behaviors (regardless of weight status) may further reduce children's obesity risk. To be included, caregiver-child dyads will have to meet the following inclusion criteria:

- Caregiver enrolling in the trial is 18 years of age or older
- Child is 0-5 years of age
- Child has at least 1 year of eligibility remaining in the home visiting program
- Family has completed their first 90-days in the home visiting program

4.2 EXCLUSION CRITERIA

- Child has a current or prior history of a feeding or growth disorder
- Caregiver has lost a significant amount of weight (>15 pounds) in the past 6 months unrelated to childbirth

4.3 SCREEN FAILURES

Caregiver-child dyads who do not meet study inclusion criteria will be informed of this decision by their parent educator and reassured that their family will still be in the home visiting program and this will not change the quality of the services and care you receive.

4.4 STRATEGIES FOR RECRUITMENT AND RETENTION

Individuals who are enrolled in the First Teacher Home Visiting program and who have completed their initial 90-day home visiting program benchmark testing will constitute our initial recruitment pool. Home visitors will approach their families who are potentially eligible to introduce the study, gauge interest, and screen interested families for eligibility. Designated study staff determine of families are eligible based on the completed screening form and inclusion/exclusion criteria. Home visitors are informed of family's eligibility and notify the family. Eligible families are then introduced to a blinded study assessment worker who schedules the enrollment and baseline visit.

The unique relationship between home visitors and mothers facilitates retention. Many of these caregivers are socially isolated and home visitors are important sources of support. We will also use strategies (implemented with participants in both intervention arms) that we have found effective for retention: (1) providing gift cards of $100 at each data collection for all caregivers, with all incentives paid after each assessment; (2) ensuring frequent contacts with all participants to maintain engagement and foster open communication; (3) sending holiday newsletters to update participants about study activities; (4) acknowledging birthdays and milestones; (5) providing reminder phone calls before assessment sessions; and (6) seeking contact information of relatives or friends to be able to reach participants.

5 STUDY INTERVENTION

5.1 STUDY INTERVENTION(S) ADMINISTRATION

5.1.1 STUDY INTERVENTION DESCRIPTION

Table 1 outlines the components of the two study arms.

Table 1. Components of each study arm		
	Standard home visiting (Control Group)	**Standard home visiting + HABITS (Intervention Group)**
Early childhood education and school readiness	X	X
Parenting	X	X
Socioemotional development (e.g., regulate emotion & behavior, develop empathy)	X	X
Physical development (e.g., immunization; motor skills)	X	X
Limit fried foods		X
Limit sugar-sweetened beverages		X
Increase daily steps		X
Increase non-starchy vegetables and fruits		X
Self-monitoring of weight and target behaviors (caregivers only)		X

Standard home visiting curriculum. Our partner home visiting program, First Teacher Home Visiting Program meets the Department of Health and Human Services (DHHS) criteria for an evidence-based early childhood home visiting service delivery model (http://homvee.acf.hhs.gov). Caregivers and children receive monthly or bi-monthly visits and they are provided with a set of carefully developed curriculum, books and materials designed to strengthen children's cognitive skills, early literacy skills, social/emotional and physical development. These voluntary services are free of charge for mothers and children (ages 0-5 years) most at risk of disparities because of poverty, social isolation, lack of material and social support, lack of transportation and limited education and literacy.

HABITS curriculum (Intervention). HABITS focuses on healthy weight of all mothers, regardless of baseline weight status, and on preventing obesity through the promotion of healthy behaviors in early childhood. Accordingly, HABITS addresses habit-formation of four behaviors relevant to mothers and children: (1) limit fried foods; (2) limit sugar-sweetened beverages (SSB); (3) increase daily steps; and (4) increase fruits and vegetables (Table 2). These behaviors are consistently associated with long-term weight management, are amenable to habit formation, and have health benefits for all mothers and children, regardless of weight status (i.e., eating fruits and vegetables as substitutes for energy-dense fried foods benefit everyone, not only obese individuals). HABITS also addresses mothers' self-monitoring of weight and targeted behaviors to support habit-formation of eating/activity behaviors. Regular self-weighing and completion of food/activity records are associated with program adherence and successful weight management.

HABITS is also ecologically relevant in strategically modifying contextual cues in the home environment (choice architecture) to support habit-formation of targeted behaviors (e.g., acquiring and preparing fruits and vegetables is a prerequisite to automatically consuming fruits and vegetables). Specifically, the intervention targets three features of choice architecture relevant to the 5 behaviors targeted by HABITS: (1) availability (i.e., items exist in the home regardless of whether they are readily visible or accessible), (2) accessibility (i.e., items are easily retrievable, ready to use/eat, located within reach), and (3) visibility (i.e., items are easy to see on countertop, or when opening the refrigerator, freezer or cupboard in the case of foods/beverages; or visible by the door or other location in the case of walking-related stimuli/cues and self-monitoring materials).

Table 2. HABITS target behaviors, scientific premises and intervention description

Scientific premise	Intervention
Behavior #1: Limit fried foods	
Fried foods are energy-dense and contain a large amount of saturated fat. Higher consumption of high-saturated fat is associated with greater weight gain and poorer health.	***Habit-formation:*** Mothers will be provided corrective feedback and instruction to recognize fried foods, adopt alternative cooking methods, and modify their favorite recipes. Didactic learning and recommendations will be supported by experiential, hands-on and learn-by-doing practice activities involving both mothers and children. Food selection and cooking methods will then be repeated until mastery and automaticity are reached. Similar habits will be shaped, practiced, and repeated to address food selection outside the home. ***Home environment:*** The foods available at home and knowledge of cooking methods are key determinants of mothers' and children's food choices. Mothers will be encouraged to avoid bringing pre-made fried foods into the home, limiting access to ingredients necessary for frying foods, and promoting access to recipes and ingredients for alternative cooking methods.
Behavior #2: Limit sugar-sweetened beverages (SSB)	
Higher SSB consumption, which may lead to excess energy intake, is associated with greater weight gain and poorer health. Guidelines recommend that adults limit their SSB consumption and that fruit juice be limited to <4 ounces/day for children under the age of 3.	***Habit-formation:*** Mothers will be taught to decrease SSB consumption for themselves and their child by making water consumption a habit (e.g., consuming water at every meal) and providing alternative non-sweetened beverages. ***Home environment:*** Mothers will be taught to avoid buying or storing SSB at home. When SSB are present in the home, mothers will identify an inconvenient/inaccessible/hidden location for storage.
Behavior #3: Increase daily steps	
Guidelines recommend adults engage in 150 minutes of moderate intensity physical activity/week. Walking is easily performed and does not require specific skills or equipment. Walking 10,000 steps/day is consistent with ~60 minutes of brisk walking. Guidelines for infants (6-12 months): daily planned activities, like tummy time, 30 minutes/day of supervised but free play, and the opportunity to crawl and move around. Toddlers & Preschoolers (1-3 years): active for at	***Habit-formation:*** Mothers will be given pedometers and instructed to work towards accumulating 10,000 steps/day in making walking a habit in response to family-relevant cues and contexts. Mothers will receive corrective feedback to help them recognize contextual cues eliciting lifestyle activities. For example, "stairs" or "talking on the phone" will become cues eliciting "walking up the stairs" or "pacing while on the phone". Mothers will be coached to make children's activity/play a daily habit integrated in the family routine and in response to daily habitual cues or contexts (e.g., 10-min of play after breakfast). ***Home environment:*** Lack of resources and safety are salient barriers to physical activity. The choice architecture of the larger family environment (home & neighborhood) will be addressed in helping mothers design and select activities around their local environment, schedule, and preferences, and to optimize their use of safe spaces. Mothers will be provided with information about resources and

least 1 hour/day (2-3 hours or more is better), and avoid sitting or lying down for >1 hour at a time, except when sleeping. Young children (4-6 years): at least 1 hour/day of physical activity (up to several hours) and avoid sitting or lying down for >2 hours at a time, except when sleeping.	free group activities conducive to physical activity (e.g., parks, walking clubs, outings), and classes they can take with their children and other home visiting families. We also consider *mothers* as key social contributors of children's choice in providing access and opportunities for their children to be physically active.
Behavior #4: Increase intake of non-starchy vegetables and fruits	
Fruits and vegetables are low in energy density, high in fiber, and generally contain more nutrients than other food groups. Eating low-energy dense fruits and vegetables daily *as substitutes for high energy-dense alternatives* can help individuals feel satisfied while reducing overall energy intake.[29,30] Most children and adults eat fewer fruit and vegetable servings than are recommended, and children are more likely to consume fruits and vegetables if these foods are introduced early. The most simplified version of the USDA's recommendation is to fill half of the plate with fruits and vegetables for every meal and each snack. This simple visual guideline does not require any counting or measuring of food.	***Habit-formation:*** Mothers will be instructed to consistently consume fruits and non-starchy vegetables as snacks (cue/ context) and to provide non-starchy fruits and vegetables at every meal (cue/ context). To do so, mothers will learn to (1) recognize snacks and meals as contextual cues eliciting fruits and vegetables consumption, and (2) prepare/cook/store non-starchy fruits and vegetables for themselves and for their young children. Corrective feedback from home visitors will be supported by learn-by-doing, hands-on activities such as taste tests and food preparation, cooking and storing demonstrations involving both mothers and children to promote multi-sensory exposure and increase children's acceptance of novel fruits and vegetables. ***Home environment:*** Families enrolled in home visiting programs receive assistance from WIC and the food bank. These organizations help promote fruits and vegetables availability for mothers and their young children. However, lack of exposure and knowledge on how to prepare and store these foods are critical constraints influencing these mothers and children's nutritional choices. Home visitors will work with mothers to ensure that the fresh, frozen, and/or canned fruits and vegetables they receive from WIC and the food bank are properly prepared, readily available, highly visible, and easily accessible in the home (e.g., prepared for convenience). Proper food preparation and storage (e.g., freezing) can also reduce food waste of perishable fruits and vegetables and ensure that families have fruits and vegetables available throughout the month. For example, cooking and freezing meals containing fruits and vegetables ensure availability despite financial constraints near the end of the month.
Behavior #5: Self-monitoring of weight and targeted behaviors (mothers only)	
Grounded in self-regulation theory, self-monitoring of weight and related behaviors (e.g., food intake) provides immediate feedback, allows for corrective actions, and are foundational components of evidence-based weight management programs. Regular self-weighing and completion of food/activity records are associated with program adherence and successful weight management.	***Habit-formation:*** Mothers will receive simplified self-monitoring forms with instruction to record weight and HABITS behaviors daily: number of fried foods, SSB, steps, and F/V servings. They will practice monitoring with their home visitors who will provide corrective feedback. Mothers will be instructed to weigh themselves at the same time each day in the same context (e.g., in the bathroom after brushing teeth). Similarly, they will be instructed to pair dietary self-monitoring with meals/snacks and to write down their step counts before bed (cue/context). ***Home environment:*** Mothers will be encouraged to place scales in highly visible and accessible locations, in close proximity to cues eliciting other well-established behaviors (e.g., beside the toilet). Mothers will be instructed to keep their self-monitoring checklist with them to ensure tracking occurs in close temporal proximity with the target behavior. Additional tips will be discussed, such as taking a picture of one's meal for later recording when necessary. With support and guidance from home visitors, posting of weight and target behavior graphs in visible locations (e.g., bathroom mirror, refrigerator door) to monitor progress will also be encouraged.

5.1.2 DOSING AND ADMINISTRATION

Families in both groups receive home visits with their home visitors at least monthly, but in most cases two home visits are completed per month. Due to the COVID-19 pandemic, some home visits may need to be completed remotely by telephone or video calls. Information on the frequency of completed home visits (dates of completed visits) and type of visit (in-person or remote visit) will be documented by home visitors as part of their standard home visiting responsibilities.

Home visitors randomized to the HABITS intervention group will be instructed to contact their families weekly between home visits by text, telephone, or video call to briefly check-in with the caregiver about how they are doing with their HABIT and work with the caregiver (as needed) to briefly problem-solve challenges. Home visitors will be instructed to document the date and type (text, telephone, video call) of every check-in completed with families.

5.2 MEASURES TO MINIMIZE BIAS: RANDOMIZATION

Randomization will be at the level of the home visitors (cluster randomization). Home visitors (n=18) will be randomly assigned to deliver the home visiting standard curriculum with HABITS (n=9 home visitors) or without HABITS (n=9 home visitors). The likelihood of bias related to cluster randomization (i.e., by home visitors) is reduced because all mothers are low-income with a relatively equal number of African American and White mothers. To reduce the risk of contamination between treatment arms, the training and supervisions of home visitors assigned to each arm of the trial will be conducted separately (i.e., to prevent sharing of HABITS material with home visitors assigned to deliver the control arm).

5.3 STUDY INTERVENTION COMPLIANCE

Home visitors randomized to deliver the HABITS intervention will complete a weekly checklist documenting all study-related intervention contacts with participants. As part of these checklists, home visitors will report the type of contact (home visit in-person, home visit by telephone, home visit by video call, or weekly check-in between home visits). For each home visit completed, home visitors will report the topics discussed and time spent discussing each topic.

6 STUDY INTERVENTION DISCONTINUATION AND SUBJECT DISCONTINUATION/WITHDRAWAL

6.1 DISCONTINUATION OF STUDY INTERVENTION

Participants will continue to receive the study intervention for the 12-month trial, as long as they remain in the home visiting program. The study intervention may be discontinued for a participant if a clinical adverse event (AE) or other medical condition or situation occurs such that continued participation in the study intervention would not be in the best interest of the subject.

6.2 SUBJECT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Subjects are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue or withdraw a subject from the study for the following reasons:

- Significant study intervention non-compliance
- If any clinical adverse event (AE) or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the subject

Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study, will not be replaced.

6.3 LOST TO FOLLOW-UP

A subject will be considered lost to follow-up if he or she fails to return for 2 scheduled visits and is unable to be contacted by the study staff.

The following actions must be taken if a subject fails to be available for a required study visit:

- The site will attempt to contact the subject and reschedule the missed visit and counsel the subject on the importance of maintaining the assigned visit schedule and ascertain if the subject wishes to and/or should continue in the study.
- Before a subject is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the subject (where possible, 3 telephone calls and, if necessary, a certified letter to the subject's last known mailing address or local equivalent methods). These contact attempts should be documented in the subject's study file.
- Should the subject continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 STUDY ASSESSMENTS

All caregiver-child dyads in the study will complete three (3) assessments: 1) Visit 1 (baseline) at the start of the study, 2) after 6 months (Visit 2), and 3) after 12 months (Visit 3). Blinded assessment staff (assessment workers) will work with families to complete these assessments. Assessments may be done completely in-person at a family's home, a combination of over the phone and in-person, or all remotely with no in-person, physical contact. The visits will include surveys and other measures described below:

- Intake and Demographics Survey (Visit 1 only): Asks questions about age, education, income level, race, medical history.
- The Physical Activity Readiness Questionnaire [PAR-Q] (Visits 1 and 2): Assesses health and ability to do physical activities. If there are any concerns about a caregiver's ability to participate in the walking and movement section of the Habits program, they may be asked to see a doctor about their health before taking part in this section of the program. They will still be able to participate in other parts of the program.[75]
- Behavior Rating Inventory of Executive Function for Adults [BRIEF-A) (All 3 visits): Caregivers will complete this validated questionnaire that asks about attention and how they react to different situations.[76]
- Medical Changes Survey: (Visits 2 and 3): Caregivers will be asked to report any medical or health changes that might have happened since the caregiver and child first started the study.

- Self-Report Behavioural Automaticity Index [SRBAI] (All 3 visits): A four-item automaticity scale that assesses automaticity of HABITS target behaviors for the caregiver and for the caregiver encouraging the child to engage in each target behavior.[77]
- Weight measurements (All 3 visits): Mothers' and child's weight will be measured in duplicate using an electronic scale (Model BWB-800S, Tanita, Portage, MI) according to standard procedures.[78]
- Height measurements (All 3 visits): Caregiver height will be measured in duplicate using a portable stadiometer (Seca 213, Perspective Enterprises) according to standard procedures.[78] When a height measurement is not possible (due to COVID-19 restrictions), caregivers will be asked to self-report their height.
- Patient Health Questionnaire-8 [PHQ-8] (All 3 visits): Assesses caregiver's thoughts and feelings over the last two weeks.[79]
- Food and Activity Frequency Survey (All 3 visits): To best capture maternal feeding practices related to behaviors targeted by HABITS, mothers will complete modified versions of the Children's Dietary Questionnaire[80] and Diet and Behavior Questionnaire (DBQ)[81] of the National Health and Nutrition Examination Survey. These instruments will be modified to focus on the eating behaviors targeted by HABITS: SSB, fried foods, and fruits and vegetables.
- Home Food and Activity Environment Assessment (All 3 visits): A modified version of the Home Food Assessment (HFA) and Home-Inventory Describing Eating and Activity Development (Home-IDEA) adapted to HABITS target behaviors will be used by assessment workers to assess accessibility and visibility of fruits, vegetables, fried food, SSB, and activity-related stimuli/cues (e.g., stroller). Items are coded as "yes" or "no" on availability. Both instruments have been validated in the homes of families with children. The Home Food and Activity Environment Assessment may be completed in-person in the family's home or (if needed to abide by COVID-19 safety guidelines) by telephone.[82-85]

Caregiver-Child benchmark data and home visit completion data will be collected from the First Teacher Home Visiting Program to ensure the study does not affect family services. For this, First Teacher Home Visiting Program will provide us with their assessments that are done as part of the standard First Teacher Home Visiting Program yearly evaluations. These questionnaires are not part of our study assessments.

7.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

7.2.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

7.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death
- A life-threatening adverse event (of note, the term "life-threatening" refers to an event in which the subject was at risk of death at the time of the event, rather than to an event which hypothetically might have caused death if it were more severe)
- inpatient hospitalization or prolongation of existing hospitalization

- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- or a congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

7.2.3 CLASSIFICATION OF AN ADVERSE EVENT

7.2.3.1 SEVERITY OF EVENT

For adverse events (AEs), the following guidelines will be used to describe severity:

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

7.2.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the clinician who examines and evaluates the subject based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

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

7.2.3.3 EXPECTEDNESS

The Principal Investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

7.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study subject presenting for medical care, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate Adverse Event Reporting form. Information to be collected includes event description, time of onset, Principal Investigator's assessment of severity, relationship to study intervention, and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the subject is enrolled will be considered as baseline and not reported as an AE. However, if the study subject's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The Study Coordinator will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study time point, the Study Coordinator will inquire about the occurrence of AE/SAEs since the last assessment.

7.2.5 ADVERSE AND SERIOUS ADVERSE EVENT REPORTING

All serious adverse events must be reported to the IRB according to regulatory requirements. The Principal Investigator will immediately report to the sponsor any serious adverse event, whether or not considered study intervention related, including those listed in the protocol or package insert and must include an assessment of whether there is a reasonable possibility that the study intervention caused the event. Study endpoints that are serious adverse events (e.g., all-cause mortality) must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship between the study intervention and the event (e.g., death from anaphylaxis). In that case, the investigator must immediately report the event to the sponsor.

All serious adverse events (SAEs) will be followed until satisfactory resolution or until the Principal Investigator deems the event to be chronic or the subject is stable. Other supporting documentation of the event may be requested and should be provided as soon as possible.

7.3 UNANTICIPATED PROBLEMS

7.3.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-

approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.3.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB within 10 working days of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB within 10 working days of the investigator becoming aware of the problem.

8 STATISTICAL CONSIDERATIONS

8.1 STATISTICAL HYPOTHESES

- Primary Endpoint(s): The primary aim of this study is to compare the effects of treatment on children's and mothers' weight outcomes at 6- and 12-months. Hypothesis 1a: Mothers receiving HABITS will have a lower weight than mothers receiving standard services. Hypothesis 1b: Children receiving HABITS will have slower weight gain than children receiving standard services.

- Secondary Endpoint(s): The secondary aim of this study is to compare the effects of treatment on maternal feeding practices, habit strength of targeted behaviors, and features of the household environment relevant to targeted behaviors at 6- and 12-months. Hypothesis 2: Compared to standard services, HABITS will result in heathier maternal feeding practices (less fried foods and SSB; more vegetables/fruits), greater habit strength of targeted behaviors, and greater home availability of cues that support targeted behaviors

8.2 SAMPLE SIZE DETERMINATION

The power analysis is prepared for comparing means of weight change from baseline to 12-months between the control and HABITS study arms. A sample size of 59 dyads per group, total of 118 dyads, will have 80% power to detect that mean of weight change in the control is 0.53 standard deviation

apart from that in HABITS by performing two-sided t-test of equal means at α=0.05. Since participants will be nested in 18 home visitors, the unadjusted calculated sample size must be further increased by an inflation factor to account for clustering due to home visitors. The inflation factor is given by the following equation: *IF = [1 + (m – 1) p]*, where *m* represents the number of participants per home visitor, and *p* represents the intraclass correlation coefficient (ICC), the ratio of between-home visitors and total variability. In this study, we assume ICC is 0.01 consistent with typical values of ICC in community-based studies.[86] By considering a 15% attrition rate between baseline and 12-month follow-up, the required total sample size is 140 (70 dyads per group). If ICC is weaker or attrition rate is smaller than we expected, we will have stronger power to detect the same difference of means.

8.3 STATISTICAL ANALYSES

At each time of measurement, descriptive statistics and measures of association will be used to summarize demographic characteristics and outcome measures. The analysis will also include graphical and statistical analysis of outlying observations and distributional characteristics of variables. Differences in outcomes of interest between the control and HABITS will be assessed by t-test of equal means and Chi-square test of equal proportions for continuous, ordinal, and categorical values, respectively.

For hypothesis 1 (primary outcomes), weight of mother or child between baseline and the 6-month and 12-month timepoints will be calculated and summarized by tabulating and plotting descriptive statistics by the study arms. Linear association of HABITS with weight changes will be estimated and adjusted for demographic information and other measured covariates by performing mixed regression models with home visitors as a random effect.

For hypothesis 2 (secondary outcomes), the analyses approach planned for Aim 1 will be used for determining if HABITS is associated with changes in maternal feeding practices, habit strength of targeted behaviors, or the household environments between baseline and 6- or 12-month follow-up.

Missing data will be addressed using multiple imputation and/or full information maximum likelihood estimation. Psychometric properties of the study scales will be investigated to ascertain appropriate validity and reliability. All statistical analyses will be performed using the most current version of SAS 9.4. Final results will be determined to be statistically significant when the accompanying statistical test yields a two-tailed probability of 0.05 or less.

8.3.1 GENERAL APPROACH

At each time of measurement, descriptive statistics and measures of association will be used to summarize demographic characteristics and outcome measures. The analysis will also include graphical and statistical analysis of outlying observations and distributional characteristics of variables. Differences in outcomes of interest between the control and HABITS will be assessed by t-test of equal means and Chi-square test of equal proportions for continuous, ordinal, and categorical values, respectively. Primary and secondary outcomes will be assessed using mixed regression models with home visitors as a random effect with adjustment for relevant demographic information and other measured covariates.

8.3.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

For the primary endpoints, weight of mother or child between baseline and the 6-month and 12-month timepoints will be calculated and summarized by tabulating and plotting descriptive statistics by the study arms. Linear association of HABITS with weight changes will be estimated and adjusted for demographic

information and other measured covariates by performing mixed regression models with home visitors as a random effect.

8.3.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

For the secondary endpoints, the analyses approach planned for primary endpoints will be used for determining if HABITS is associated with changes in maternal feeding practices, habit strength of targeted behaviors, or the household environments between baseline and 6- or 12-month follow-up.

8.3.4 SAFETY ANALYSES

Rates and severity of adverse events will be summarized using descriptive statistics and compared between study arms by Chi-square test of equal proportions.

8.3.5 BASELINE DESCRIPTIVE STATISTICS

At baseline, descriptive statistics will be used to summarize demographic characteristics and outcome measures by study arm and for the entire sample. The analysis will also include graphical and statistical analysis of outlying observations and distributional characteristics of baseline descriptive variables. Differences in baseline characteristics of interest between the control and HABITS will be assessed by t-test of equal means and Chi-square test of equal proportions for continuous, ordinal, and categorical values, respectively.

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

9.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO SUBJECTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the subject and written documentation of informed consent is required prior to conducting study screening procedures. A separate screening consent form will not be used.

9.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the subject will be asked to read and review the document. The investigator will explain the research study to the subject and answer any questions that may arise. A verbal explanation will be provided in terms suited to the subject's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research subjects. Subjects will have the opportunity to carefully review the written consent form and ask questions prior to signing. The subjects should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The subject will sign the informed consent document prior to any procedures being done specifically for the study. Subjects must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the

informed consent document will be given to the subjects for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the subject undergoes any study-specific procedures. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

9.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study subjects and the Institutional Review Board (IRB), will provide the reason(s) for the termination or suspension. Study subjects will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the IRB.

9.1.3 CONFIDENTIALITY AND PRIVACY

Subject confidentiality and privacy is strictly held in trust by the participating investigators and their staff. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the Principal Investigator.

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

Representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the subjects in this study. The clinical study site will permit access to such records.

The study subject's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB and/or Institutional policies.

Study subject research data, which is for purposes of statistical analysis and scientific reporting, will be stored at the UAB Department of Medicine, Division of Preventive Medicine research office. This will not include the subject's contact or identifying information. Rather, individual subjects and their research

data will be identified by a unique study identification number. The study data entry and study management systems used by research staff will be secured and password protected.

9.1.4 QUALITY ASSURANCE AND QUALITY CONTROL

The site will perform internal quality management of study conduct, data collection, documentation and completion. Quality control (QC) procedures will be completed by the Data Manager during data entry into REDCap. Any missing data or data anomalies will be communicated to the Study Coordinator for clarification/resolution.

Following written Standard Operating Procedures (SOPs), the MPIs and research team will verify that the trial is conducted and data generated are collected, documented (recorded), and reported in compliance with the protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), and applicable regulatory requirements.

The site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and inspection by local and regulatory authorities.

9.1.5 DATA HANDLING AND RECORD KEEPING

9.1.5.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the trial staff at the site under the supervision of the Principal Investigator. The Principal Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

Hard copies of source document worksheets will be used for recording data for each subject enrolled in the study.

9.1.5.2 STUDY RECORDS RETENTION

Study documents should be retained for a minimum of 3 years after the completion of the study. These documents should be retained for a longer period, however, if required by local regulations.

9.1.6 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol requirements. The noncompliance may be either on the part of the subject, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the Principal Investigator to use continuous vigilance to identify and report deviations within 10 working days of identification of the protocol deviation. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The Principal Investigator is responsible for knowing and adhering to the reviewing IRB requirements.

9.1.7 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

9.2 ABBREVIATIONS

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
DHHS	Department of Health and Human Services
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
LSMEANS	Least-squares Means
NCT	National Clinical Trial
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities
SOP	Standard Operating Procedure
SSB	Sugar-Sweetened Beverage
UP	Unanticipated Problem
US	United States

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UAB IRB
Approved
10-Mar-2022
until
09-Mar-2023

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: **Healthy Homes, Healthy Habits: A Home Visitation Program to Improve Health for Families**

UAB IRB Protocol #: IRB-300001353

Principal Investigator: **Gareth Dutton, PhD**

Sponsor: National Institute on Minority Health and Health Disparities

General Information	You and your child are being asked to take part in a research study. This research study is voluntary, meaning you and your child do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is test if a program we call "Healthy Homes, Healthy Habits" helps families like yours start habits for healthy eating and physical activity.
Duration & Visits	You and your child will be in this study for 12 months.
Overview of Procedures	This study will include your and your child's normal home visits as part of the home visit program you and your child are in, as well as 3 assessment visits to collect information related to healthy habits at the start of the study, after 6 months, and after 12 months.
Risks	The most common risks may include minor and temporary injury, such as spraining your ankle from exercise. This is not common, and you will only be asked to make changes that are comfortable for you.
Benefits	You may or may not benefit from being in this study.
Alternatives	If you do not want to take part in the study, you and your child will still be seen for your regular home visiting program visits.

Purpose of the Research Study

We are asking you to take part in a research study with your child because you are receiving home visiting services and your child is no more than 5 years old and eligible to remain in the First Teacher Program for up to a year. Please take as much time as you need to read this form. You may want to talk about the study with your family, friends, or with the Family Guidance Center staff. If you do not understand parts of this form, please ask questions. The study team wants to know if a program called "Healthy Homes, Healthy Habits" ("Habits" for short) helps families like yours develop healthy habits. About 300 families will be enrolled in this study.

Study Participation & Procedures

If you agree to be in the study, we will ask you questions about your and your child's eating and physical activity habits. We will also collect information about the foods and activity equipment you have in your home. All families in the study will continue to receive home visits and they will continue to work with a parent educator to meet the goals of the program.

If you decide to be in our study with your child, you and your child will be *randomly assigned* by a computer to one of two groups. This means that you and your child have an equal chance of being in either study group, and which group you and your child are in is based on chance, like flipping a coin. The two possible study groups are: (1) the *standard home visiting program only*, or (2) *the standard home visiting program + Habits*.

If you and your child are in the group that gets the "standard home visiting program only", you and your child will keep getting the same home visit services without changes. If you and your child are in the "standard home visiting program + Habits" group, you and your child will get the home visit program AND the healthy habits program. The Habits program is a 10-20 minute program delivered by your parent educator during your regular home visits. Those assigned to the Habits program will learn about how their family can eat more fruits and vegetables, eat less fried foods, drink less sugary drinks, cook tasty budget-friendly food with healthy ingredients, and find fun and easy ways to be more active with their families. If you are assigned to the "*standard home visiting program + Habits*" group, your parent educator will also collect your weight every week as part of the study.

Assessments:
All families in the study will complete three (3) assessments: 1) at the start of the study, 2) after 6 months, and 3) after 12 months. Home visiting staff, called assessment workers, will work with you to complete these assessments. Assessments may be done completely in-person at your home, a combination of over the phone and in-person, or all remotely with no in-person, physical contact. The visits will include surveys and other measures described below.

Intake and Demographics Survey (Visit 1 only, 10-15 minutes): Asks questions about your age, education, income level, race, medical history.

PAR-Q Survey (Visits 1 and 2, 5 minutes): Assesses your health and ability to do physical activities. If there are any concerns about your ability to participate in the walking and movement section of the Habits program, you may be asked to see a doctor about your health before you take part in this section of the program. You will still be able to participate in other parts of the program.

BRIEF Survey (All 3 visits, 15-25 minutes): You will complete a questionnaire that asks about your attention and how you react to different situations.

Medical Changes Survey: (Visits 2 and 3, 5-15 minutes): Assesses medical or health changes that might have happened since you first started the study.

Self-Reported Habit Index Surveys (All 3 visits, 15-25 minutes): Assesses eating and activity habits.

Height and weight measurements (All 3 visits, 10-20 minutes): We will measure your and your child's weight and height/length. When a height measurement is not possible, we may ask you to estimate your height.

PHQ-8 Survey: (All 3 visits, 5 minutes): Assesses your thoughts and feelings over the last two weeks.

Food and Activity Frequency Survey (All 3 visits, 10-15 minutes): Assesses how often you and your child eat certain types of foods and are physically active.

Home Food and Environment Assessments (All 3 visits, 30-45 minutes): Assessment staff will review with you the foods, drinks, and activity items you have in your home. They may ask you to show them where you keep certain foods or drinks.

Trust in Parent Educator Survey (Visits 2 and 3, 3-5 minutes): You will complete a questionnaire that asks about how long you have known your parent educator and the level of trust you have with your parent educator.

We will also monitor your and your child's progress in the First Teacher Home Visiting Program to ensure the study does not affect your services. For this, First Teacher Home Visiting Program will provide us with their assessments that are done as part of the standard First Teacher Home Visiting Program yearly evaluations. These questionnaires are not part of our study assessments.

If you are participating in the group that receives the "standard home visiting program + Habits", we will also ask you to record your healthy habits and daily weight as a way to help you keep track of your progress. We will collect this information to help us learn how people create habits.

Your de-identified private information (private information with all identifiers removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent. **This is only when there are no identifiers associated with the data.**

Risks and Discomforts

The risks to you and your child for participating in this study are judged to be low but include minor and temporary injury, such as spraining your ankle from exercise. This is not common, and you will only be asked to make changes that are comfortable for you. If this type of injury happens or you have an injury not related to being in the study, you can stop participating in the study at any time, or only participate in parts of the program until you recover.

Some questions on the surveys ask about personal information, such as income and information about your health. There is a small risk that you will feel uncomfortable or not want to answer these questions. If this happens, you can choose to skip any questions at any time. If our staff feels that you may be under distress or might need additional help, they will work with your parent educator to connect you to additional services and/or offer referrals to someone who can help you and/or your child.

Information for Women of Childbearing Potential, Nursing Mothers, and/or Men Capable of Fathering a Child

If you become pregnant during the study or are nursing, you will continue to be allowed to participate in the program. The information on diet and healthy activity does not cause any extra risk to you or your baby and does not affect mother's milk supply.

Benefits

You may not benefit directly from taking part in this study. However, if you are assigned to the "*standard home visiting program + Habits*" group it is possible that you may learn skills that help your family to have healthy habits. These healthy habits may help you improve what you and your child eat and how active you and your child are. You may also feel good about helping to develop a health program for families like yours. Your parent educator will be randomly assigned (like the flip of a coin) by a computer to either provide the nutrition and physical activity material (Habits) and the First Teacher Home Visiting Program material, or to provide just the usual First Teacher Home Visiting Program material. You will be assigned to receive the First Teacher Home Visiting Program or the First Teacher Home Visiting Program + Habits by chance. We do not know if one intervention program will help you more than the other, and we do not know which program will be more effective for reaching the First Teacher Home Visiting Program educational goals or the Habits health goals. Because your parent educator will be assigned to provide these programs by chance, it is possible that your group may have more or less benefits than the other study group.

Alternatives

Your alternative is to not participate in this study. If you decide not to be in this study, you would still be seen for your regular home visiting program visits.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study researchers must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

A description of this study will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at the University of Alabama at Birmingham or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham (UAB) - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Minority Health and Health Disparities which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you and your child take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. If you decide to stop being in the study, you and your child will still receive home visiting services, but you and your child will not receive the Habits program and we will not collect study assessments.

You and your child are free to withdraw from this research study at any time. Your choice to leave the study will not affect your or your child's relationship with UAB or the home visiting program. Contact your parent educator if you want to withdraw from the study.

You and your child may be removed from the study without your consent if the sponsor ends the study, if the researchers decide it is not in the best interest of your or your child's health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you or your child for taking part in this study.

Payment for Participation in Research

You will be paid $100 for completing each of the three assessments. If you and your child complete all of these assessments, you will receive a total of $300. If you and your child withdraw from the study, you will be paid $100 for each data collection visit that you and your child completed. We will try to pay you immediately after each data collection visit, or we will mail your payment to you within a few weeks of completing these visits. The total payment you can receive is $300. If you or your child do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research, please call Dr. Gareth Dutton at (205) 934-6876. You can also contact the research program coordinator at (205)-975-7274.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you can call the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree for you and your child to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Parent Participant Date

_____

Signature of Person Obtaining Consent Date

Waiver of Assent

The assent of _____ (name of child/minor) was waived because of:

Age _____ Maturity _____ Psychological state of the child _____