Published in final edited form as:

Contemp Clin Trials. 2018 July ; 70: 88–98. doi:10.1016/j.cct.2018.05.015.

Habit Formation Intervention to Prevent Obesity in Low-Income Preschoolers and Their Mothers: A Randomized Controlled Trial Protocol

Sarah-Jeanne Salvy, PhD[#],

Division of Preventive Medicine, University of Alabama at Birmingham, Medical towers 616, 1717 11th, Avenue south, Birmingham, Alabama 35205, United States, ssalvy@uabmc.edu, Phone: 205.934.7609

Gareth Dutton, PhD[#],

Division of Preventive Medicine, University of Alabama at Birmingham, Medical towers 615, 1717 11th Avenue south, Birmingham, Alabama 35205, United States, gdutton@uabmc.edu, Phone: 205.934.6876

Alena Borgatti, and

Division of Preventive Medicine, University of Alabama at Birmingham, Medical towers 621, 1717 11th Avenue south, Birmingham, Alabama 35205, United States, aborgatti@uabmc.edu, Phone: 205-975-7274

Young-il Kim, PhD

Division of Preventive Medicine, University of Alabama at Birmingham, Medical towers 616, 1717 11th Avenue south, Birmingham, Alabama 35205, United States, youngkim@uab.edu, Phone: 205.975.6695

[#] These authors contributed equally to this work.

Abstract

Authors' Contributions

Drs. Salvy and Dutton designed the study and the intervention content and wrote the first draft of the manuscript. Dr. Kim help designed the analytic plan and will oversee the data analysis in collaboration with Drs. Salvy and Dutton. Alena Borgatti manages the day-to-day running of the study and contributed to the editing of the manuscript. All authors read and approved the final manuscript.

Competing Interest Statement

The authors declare that they have no conflict of interest or competing interests pertinent to this study. The authors have no financial relationships relevant to this article to disclose.

Trial Registration

The study is registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (Protocol Record 000517527).

Ethics Approval and Consent to Participate

The study protocol is being reviewed by the University of Alabama at Birmingham Institutional Review Board. Participants (mothers) will be required to provide informed written consent for themselves and their children before participating.

Consent for Publication

Not applicable.

Availability of Data and Material

The datasets from this study will be available from the principal investigators, Drs. Dutton and Salvy, on written request.

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Background—Low-income and racial/ethnic minority mothers and their young children are at increased risk for obesity. Lack of access to evidence-based obesity prevention and treatment services further contributes to these disparities.

Methods—This two-arm, parallel, randomized controlled trial (RCT) tests the effectiveness of a simple obesity intervention (HABITS) delivered as part of ongoing home visitation services, compared to the existing home visitation services without obesity-related content on mothers' and children's obesity risks. HABITS 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. Participants will be 298 mothers (>50% African American; 100% low income) and their children (3–5yo at baseline) enrolled in a home visitation program in central Alabama. Home visitors will be randomly assigned to deliver the home visitation curriculum with or without HABITS as part of their weekly home visits for 9 months. Assessments of mothers (weight, waist circumference, and habit strength of targeted behaviors), children (rate of weight gain), and the food/activity household environment will be conducted at enrollment, post-intervention (9 month), and one year post-intervention follow-up.

Discussion—This research is poised to have a substantial impact because the delivery modalities of current obesity efforts disproportionately restrict the reach and engagement of underserved, low-income children and their caregivers who are most at-risk for health and obesity disparities.

Keywords

Preschoolers; Obesity Prevention; Habit Formations; Home Visitation

1. Introduction

Economically disadvantaged families are disproportionately affected by obesity [1] Maternal factors such as mothers' diet and feeding practices are instrumental in shaping children's health behaviors and weight outcomes [2–6] Similarly, factors within the home environment (e.g., foods present in the home) have also been associated with children's dietary intake and weight status [7–9] Even the most successful obesity reduction/prevention strategies have had limited impact among under-resourced families, partly because effective interventions are neither accessible nor tailored to address families' needs [10, 11] Also, conventional family-based obesity interventions comprehensively address nutritional, physical activity, and behavioral topics [12–14], although a handful of behaviors (e.g., self-monitoring of weight, consistent physical activity, regular eating patterns) have been consistently associated with long-term weight management [15–19] Thus, helping individuals develop healthy habits around a few key behaviors may be as effective and more efficient. A simplified, targeted approach may be particularly well-suited for under-resourced, overburdened families [20]

This approach is also consistent with a habit-formation paradigm [20–25], which focuses on frequently and consistently enacting a target behavior in response to a specific cue until the behavior reaches automaticity [20–25] A handful of studies suggest that habit-formation interventions focused on select energy-balance behaviors are feasible and result in greater

weight loss than usual care [20, 21, 26] and are effective in improving parental feeding practices for young children [27]. Since habit-formation and automaticity rely on the repetition of a behavior in response to consistent contextual cues, it is imperative to address cues in the household environment that are conducive to the development and maintenance of targeted healthy habits. Modification of household cues (e.g., availability of prepared fruits/vegetables) to support behavior change 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*) [28–31]. Indeed, two recent trials showed promise for the effectiveness of modifications in the participants’ household environment for weight management [32, 33].

Implementing an obesity prevention program that (1) targets low-income families, (2) is designed to develop habit formation around a select number of eating and activity behaviors, and (3) includes modifications to the home environment, would ideally require partnering with an existing infrastructure to make such a program feasible. The current intervention is imbedded within an ongoing home visitation program designed to optimize child development and prevent adverse outcomes [34–38]. The home visitation infrastructure is ideal to address obesity among underserved mothers and children, as it reduces many of the barriers for the conventional delivery of obesity programs. Since these are already implemented in urban and rural areas nationwide [39–42], dissemination and scalability are feasible. Thus, the current project is designed to evaluate the effects of a home-delivered habit formation intervention targeting obesity prevention among a sample of low-income mothers and their young children (aged 3–5 years).

2. Methods

2.1. Overview of study design

The HABITS study is a two-arm randomized controlled trial involving mother-child dyads enrolled in our partner home visitation program (*Home Instruction for Parents of Preschool Youngsters, HIPPY*) in central Alabama (see Logic Model in **Table 1**). Assessment workers who enroll families in the standard home visitation program services introduce the HABITS program to all mothers requesting home visitation services and enroll interested mothers in the study. Based on standard home visiting procedures, mothers-children enrolled in home visiting services are matched to highly-trained home visitors based on their race. Home visitors, in turn, are randomly assigned to deliver the home visitation curriculum with or without HABITS (see 2.3. *Intervention arms* below) for 9 months. To avoid contamination between intervention arms, home visitors are assigned to deliver only one of the study arms, and supervision for home visitors in each arm is conducted separately. Assessment workers (masked to group assignment) will conduct study assessments of mothers, children and home environment (section 2.4 *Measurements below* at baseline, post-intervention (9 months), and one year post-intervention (study months 20–21). In addition, we will hold annual meetings with our Community Advisory Board (CAB) to discuss the implementation of the study and explore emerging issues to optimize outcomes and decrease disparities. These annual CAB meetings will also make it possible to garner the input of home visiting stakeholders to assess the feasibility of these activities in other home visitation programs.

This feedback will be documented in staged knowledge transfers to subsequently refine and tailor HABITS and plan dissemination efforts to other home visitation programs.

The study protocol is being reviewed by the University of Alabama at Birmingham Institutional Review Board. The study will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement [47], and is registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (Protocol Record 000517527).

2.2. Participant recruitment and eligibility criteria

Participants will be mothers (>50% African American, 40% White, <10% other/multiple race) and children (3–5yo at enrollment) who will be receiving home visitation services from our partner (*Figure 1*). Mothers are enrolled in these free and voluntary services through community outreach. In order to be eligible, mothers must meet a number of risk criteria such as: poverty, social isolation, lack of material and social support, lack of transportation and limited education and literacy. All families meet the federal definition for poverty, and two-thirds live in extreme poverty (50% or less of the poverty threshold). Mothers will be ineligible for the study if they are following a diet/are enrolled in a weight-loss program or are currently pregnant. Mothers/children will be ineligible if they are underweight (i.e., mother= BMI<18.5; child = < 5th percentile), have an eating/feeding disorder, schizophrenia, or an obesity-related syndrome (e.g., Prader Willi). Eligibility will be assessed via medical history as described in the section 2.4. Measurements below.

2.2.1. Recruitment/enrollment.—Assessment workers (distinct from home visitors) will introduce the study to mothers (seeking home visitation services or already receiving services), obtain written informed consent, and enroll them in the study.

2.2.2. Randomization.—Randomization will be at the level of the home visitors (cluster randomization). Home visitors (n=30) will be randomly assigned to deliver the home visitation standard curriculum with or without HABITS (15 home visitors in each intervention arm). 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). All analyses will control for home visitor years of experience.

While turnover among home visitors in the existing program is low, it can and does occur. Based on standard home visiting procedures, families who lose their home visitor are reassigned to a new home visitor. Families enrolled in the Habits study who lose their home visitor will be reassigned to a home visitor in accordance to their randomization, and they will have the opportunity to continue the study if they decide to do so. Ongoing training of new home visitors will be conducted as needed when new program staff are hired.

2.3. Intervention arms

Table 2 outlined the components of the two intervention arms.

2.3.1. Standard home visitation curriculum.—Our partner home visitation program, *Home Instruction for Parents of Preschool Youngsters* (HIPPY) program meets the Department of Health and Human Services (DHHS) criteria for an evidence-based early childhood home visiting service delivery model. HIPPY provides services to over 16,000 families in 120 communities throughout the United States (<https://www.hippyusa.org/about-us/>). Home visitation programs, such as HIPPY, are embedded in a comprehensive system of child and maternal health designed to optimize child development and prevent adverse outcomes.[34–38] These programs are effective in improving children’s physical and psychosocial health, immunization rates, breastfeeding, and overall cognitive and social development.[38, 39, 42, 48–63] *To date, however, there has been no comprehensive effort to address maternal-child nutrition and physical activity as part of home visitation services.* Consistent with a capacity building approach, the aim of this study is to extend the curriculum and mission of an ongoing home visitation program to provide health promotion and address related health disparities among low- income women and children (see also[64]) who would not receive these services otherwise.

Mothers and children enrolled in HIPPY receive in-home weekly 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 3–5yo) most at risk of disparities because of poverty, social isolation, lack of material and social support, lack of transportation and limited education and literacy.

HIPPY home visitors are selected based on their expertise with at-risk mothers and children and their personal characteristics (e.g., non-judgmental, compassionate, ability to establish a trusting relationship), and their experience working with culturally diverse, at-risk families. Home visitors receive extensive training to master the psychosocial and educational HIPPY curriculum (supported by scripted manuals) and they receive weekly supervision. The training, scripted manuals and supervision prevent drifting (i.e., avoid covering topics/areas not included in the standard curriculum). The training further covers: cultural competency, linkage to community services, provision of preventive health care and mental health referrals, establishing and maintaining trust with families, building upon family strengths, developing individual family support plans, teaching parent-child interaction, and managing crises. Home visitors have a caseload of 10–15 families, and they receive weekly supervision and ongoing developmental training to meet their families’ needs.

2.3.2. HABITS curriculum (Table 3).—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 walking and activity; and (4) increase fruits and vegetables to displace energy dense alternatives (**Table 3**). These behaviors are

consistently associated with long-term weight management [15–19], are amenable to habit formation [20–25], and have health benefits for all mothers and children, regardless of weight status [65–78] 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 [79–85]

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 five 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). Mothers and the target child are the focus of both home visitation services and HABITS; however, the intervention will engage other household members whenever possible (e.g., spouse; siblings; in-laws) to optimize adherence to recommendations.

Mothers finally learn about developmental eating stages and transitions, and healthy feeding practices to promote: (a) responsiveness to child hunger and fullness cues; (b) the consumption of nutrient-dense foods (as opposed to energy-dense); (c) following a structured schedule for meals/snacks; and (d) the use of non-food related child soothing techniques. Mothers also learn strategies to address neophobia, such as habitual and repeated multi-sensory (i.e., smell, touch, taste) exposures to nutrient-dense novel foods, gradual texture shaping, parents/caregivers modeling through mother's healthy habit development, involvement of children in food selection and preparation; and strategies to handle meal-related tantrums (e.g., redirection, positive reinforcement of appropriate behaviors).

Home visitors delivering HIPPY + HABITS receive a 2-day initial training and annual refresher courses from the PIs (Drs. Salvy and Dutton) and the early childhood Registered Dietitian. The training covers: (1) the importance, rationale, and education about the behaviors targeted, including addressing possible misinformation, (2) the concept of habit formation along with detailed instruction to form habits, and (3) practical advice specific to each targeted behaviors and application of household modifications to promote habit formation. HABITS home visitors will further be trained to adapt the material to families' cultural and individual practices and preferences (e.g., food modifications based on favorite meals; selection of relevant/tailored cues).

2.4. Measurements

Assessment workers masked to intervention assignment will conduct all assessments (*Table 4*) in the families' homes at baseline, 9 months, and one year post-intervention.

2.4.1. Demographics and medical history.—At baseline, we will assess participant demographics including maternal age, mother and child race/ethnicity, household composition, socioeconomic status (education, income), as well as maternal and child medical history. Home visitor years of experience will also be collected from our home visitation partner. These variables will be entered as covariates in the analyses.

2.4.2. Mother anthropometrics.—Mothers' weight and height will be measured using an electronic scale (Model BWB-800S, Tanita, Portage, MI) and portable stadiometer (Seca 213, Perspective Enterprises) according to standard procedures [91] We will measure height in duplicate and if measurements are not within 0.5 cm, we will obtain a third measurement. The mean of all measurements will be used to calculate Body Mass Index ($\text{BMI} = \text{kg}/\text{m}^2$). Waist circumference will be measured at the umbilicus to the nearest 1-mm using a non-stretch measuring tape.

2.4.3. Children's weight change.—Conditional weight gain score is a recommended and valid measure of rate of weight change in young children [92–94] Weight will be measured on a digital scale (Model BWB-800S, Tanita, Portage, MI). Weight-for-age z-scores will be calculated using World Health Organization Standards, as recommended by the Center for Disease Control. Conditional weight gain z-scores (normally distributed; mean of 0 and a standard deviation of 1) is calculated as the standardized residuals from the linear regression of the follow-up weight z-score on baseline weight z-score, with age, sex and birthweight as covariates (potential confounding variables). The standardized residual is the follow-up weight z-score minus its value predicted from the regression, divided by the residual standard deviation from the regression. A positive value indicates a faster, and a negative value a slower, rate of weight gain compared with the population mean weight gain.

2.4.4. Home food and activity environment.—To evaluate availability/unavailability of targeted food and beverage items, assessment workers will conduct pantry assessments using a bar code scanner to document all pantry, refrigerator, and freezer items. Bar code software, available as a smart phone application, allows for the recording of items and analysis of their nutritional content. The items without bar codes (e.g., fruits/vegetables) will be recorded (number and size of items). We will total the number of SSB, fried foods and fruits/vegetables servings found in the home. Pantry inventories are valid tools for assessing food availability [95–101] and predictive of actual food consumption and weight [7–9]

A similar approach will be used to assess availability of walking-related stimuli/cues (e.g., walking shoes, stroller) and self-monitoring materials (e.g., checklists, graphs). A modified version of the *Home Food Assessment* (HFA) [102] and *Home-Inventory Describing Eating and Activity Development* (Home-IDEA) [103, 104] adapted to HABITS target cues and behaviors will be used by assessment workers to assess accessibility and visibility of fruits/vegetables, fried food, SSB, walking related stimuli/cues (e.g., easiness to access stroller) or self-monitoring cues/materials. Both instruments have been validated in the homes of families with children [102, 104, 105], and the Home-IDEA has been specifically designed and validated to assess the food and activity environment of low-income, racially and ethnically diverse families with young children [103]

2.4.5. Habit strength.—Habit strength will be measured using a modified version of the *Self-Report Habit Index* (SRHI) to query about the five specific behaviors targeted as part of this intervention [106] The SRHI is a 12-item questionnaire assessing respondents' subjective experience of five features of habits: 1-lack of awareness, 2-lack of control, 3-efficiency, 4-history of repetition, and 5-self-identifying with the behavior. The SRHI has shown good test-retest reliability, correlates well with measures of response frequency and past behaviors, and can differentiate between behaviors that are performed with different frequencies [106] The SRHI has discriminant validity over and above past frequency of behavior in predicting future behavior [107] Habit strength assessed with the SRHI has been shown to associate with relevant health behaviors, including consumption of fruit, vegetable, and sugar-sweetened beverage [106–110] and physical activity in adults and children [111–113] SRHI has also been used to assess change in habit strength over time [23] The SRHI will be used to assess mothers' habit strength around the five targeted behaviors (self-weighing/monitoring, increase fruits and vegetables, increase daily steps, limit fried foods and limit sugary beverages/juices), as well as habit strength of mothers' parenting practices related to the behaviors targeted as part of this intervention (increase child's intake of fruits and vegetables, increase child's daily steps and activity, limit child's intake of fried foods and limit child's consumption of sugary beverages/juices).

2.4.6. Food and Activity Frequency.—Using a modified version of the Children's Dietary Questionnaire (CDQ) [114] and the Diet and Behavior Questionnaire (DBQ) from the National Health and Nutrition Examination Survey (NHANES) [115–117], mothers will report on the eating, feeding, and physical activity behaviors. These instruments will be modified to focus on the eating behaviors targeted by HABITS: SSB, fried foods, and fruits and vegetables, with additional items asking about self-weighing and physical activity. The *Children's Dietary Questionnaire* has been validated in five separate study samples, including samples of young children. The instrument has satisfactory test-retest reliability (intraclass correlation coefficient 0.51 to 0.90) and ability to detect change following a weight management intervention. The DBQ has been extensively used over the past 40 years to assess the health and nutritional status of racially, ethnically and economically diverse U.S. residents, with well-established reliability and validity [115–117] Responses will be scored to reflect the number of daily servings of SSB, fried foods, fruits and vegetables. We will test the hypothesis that HABITS will result in healthier maternal feeding and physical activity practices and examine whether maternal feeding practices mediate the relationship between HABITS and children's rate of weight gain.

2.4.7. Monitoring of HIPPY targeted benchmark outcomes.—As part of the trial, we will monitor whether the addition of the Habits module affects the benchmark areas targeted by HIPPY namely: Early childhood education and school readiness; Parenting and Socioemotional development. These domains will be assessed using standard HIPPY procedures and instruments including: the *Bracken School Readiness Assessment* - Third Edition (BSRA-3) [118]; the *Kaufman Survey of Early Academic and Language Skills* (K-SEALS) [119], the *Developmental Indicators for the Assessment of Learning*™ (DIAL™ - 4) [120]; The Ages and Stages Questionnaires (ASQ-3 and ASQ:SE-2 for social-emotional development) [121–124] and the *Protective Factors Survey* (PFS) [125] measuring Family

Functioning/ Resiliency, Social Support, Concrete Support, Knowledge of Parenting and Child Development, Nurturing and Attachment.

2.5. Analytic plan and power analysis

2.5.1. Power and sample size estimates.—The power analysis is prepared for comparing means of weight change from baseline to post-intervention (9 months) and from baseline to one year post-intervention (month 21) between the control and HABITS conditions. A sample size of 105 dyads per group, total of 210 dyads, will have 80% power to detect that mean of weight change in the control is 0.39 standard deviation apart from that in HABITS by performing two-sided t-test of equal means at $\alpha=0.05$. Since participants will be nested in 30 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 [126]. Calculating the inflation factor and adjusting the aforementioned sample size, we see that the required total sample size needs to be inflated to 223 to maintain 80% power. By considering conservative 25% attrition rate between baseline and one year follow-up, the required total sample size is 298, 149 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.

2.5.2. Statistical analysis.—The main analyses focus on comparing weight changes of mother and child between baseline, the end of the intervention (9 month) and one-year follow-up. 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. As similar analytic approach will be used to determine if HABITS is associated with changes in habit strength of targeted behaviors, or in household environments between baseline and the end of the intervention or follow-up. Three way regression models will be estimated [127] to determine if maternal weight, habit strengths, or household environments mediate the association of HABITS with change of child's weight from baseline to the end of the intervention or follow-up. The amount of mediation (indirect effect) will be estimated, tabulated, and tested by Sobel test [128] and bootstrapping. In addition to evaluating potential mediators, we will also investigate for moderator effect of race by presenting aforementioned statistics by race and evaluating interaction effect between HABITS and race in the models. Missing data will be addressed using multiple imputation and/or full information maximum likelihood estimation. All statistical analyses will be performed using the most current version of SAS. Final results will be determined to be statistically significant when the accompanying statistical test yields a two-tailed probability of 0.05 or less.

Finally, Fisher exact tests (2-sided alpha level of 0.10) will be used to compare the intervention arms on benchmark areas. If there is any unintended variation in effectiveness on any of these benchmarks which exceeds 10%, we will be able to detect this difference.

with power from 45% to 97% depending on the rate (1%–99%) of benchmark attainment in group of mothers receiving the standard HIPPY curriculum.

3. Discussion

This study is both theoretically and clinically innovative in several ways. First, to our knowledge, HABITS is the first RCT to assess the effectiveness of a habit-based intervention delivered as part of home visitation program to prevent obesity among underserved preschool-aged children and their mothers. This initiative represents a unique opportunity to increase access to obesity treatment/prevention services by leveraging an ongoing home visitation 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.

Second, this initiative focuses on a critical developmental period to intervene on children's weight trajectories. This is important as obesity in early childhood tracks into late childhood and adolescence [129–131]. Third, by targeting children and their mothers, 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. Finally, this research represents an unparalleled incubator to test the effectiveness of a habit-formation intervention implemented in the home environment (the “choice architecture”) on weight outcomes of mothers and children.

There are also a number of potential challenges and considerations related to this work. First, because this is the first study to assess the integration of habit formation into home visitation services, we considered making the inclusion criteria more stringent to increase the homogeneity of our sample. However, both researchers and stakeholders determined that all families enrolled in home visitation should be encouraged to participate in the study, with limited exclusion criteria. We elected to include all families regardless of weight status because the targeted health behaviors are relevant and beneficial for all mothers and children. Improvements in maternal behaviors (regardless of weight status) may further reduce children's obesity risk.

A second consideration is related to our choice of target behaviors. Habit-formation interventions prioritize a select number of behaviors to address mastery rather than a broader but less focused coverage of wide-ranging topics. Thus, it was necessary to identify the potentially most impactful behaviors amenable to habit-formation in the home environment. The behaviors targeted in this intervention were selected based on these considerations as well as their documented effects on energy balance and weight; applicability to both maternal and child obesity risk, regardless of current weight status; and cultural and financial relevance for low-income and minority households.

Third, we considered assessing changes in maternal and child diet and physical activity as treatment outcomes, but opted for an effectiveness approach focusing on weight as primary outcomes and on intervention mechanisms (habit strength and choice architecture of the

home environment) for several reasons: (1) objective measures of household food availability, accessibility and visibility are related to food choice, consumption, and weight status [6–9, 104, 132]; (2) questionable validity of assessing physical activity using self-report (or parent report); (3) disputed utility of conducting comprehensive 24-hour dietary recall with mothers as respondents for themselves and their children, particularly considering the time and costs of conducting multi-pass recalls; and (4) additional measures result in increased participant burden and project costs that are not well-justified given the possibility for incomplete, unreliable, and/or redundant data.

Finally, we recognize that the addition of Habits to different home visitation curricula will necessitate training for home visitors from different programs. Most importantly, the dissemination will require the input of local stakeholders and families, as they are best suited to identify the staffing and physical resources available that can be harnessed to promote healthy changes. However, Habits can easily be adapted to best suit and accommodate the needs of different ethnic and racial populations (e.g., cuisines, lifestyle activities preferences, household composition). Findings from this study will inform the feasibility and suitability of future dissemination of the intervention to other home visitation programs nationwide.

Conclusion

Over 500 publicly and privately funded home visitation programs provide services to more than 650,000 low-income, underserved children and their families in the U.S. annually. More than 40% of low-income children enrolled in federally funded programs are overweight or obese by age 5 [43–46]. Recent data further indicates that the prevalence of high Weight-For-Length among children enrolled in home visitation programs is substantially greater than that of the general U.S. population (based on NHANES data). This trend also persisted across strata based on the sex of the child, as well as across primary classifications of race-ethnicity [133]. Given the high prevalence of obesity in this priority population, childhood obesity will likely be identified as a priority to be addressed by home visitation programs nationwide. These priorities are set forth by the funder of our home visitation partner for this project (*U.S. Maternal Infant and Early Childhood Home Visiting Program*; Health Resources and Services Administration; *U.S. Department of Health and Human Services*). Based on the initial and ongoing input and support of local, state, and national home visitation directors involved in the implementation of this research, this work has strong potential for dissemination to other home visitation programs nationwide. Our multi-faceted dissemination plan is rooted in the RE-AIM (Reach, Efficacy, Adoption, Implementation, and Maintenance) [134–142] framework to optimize the scalability and the public health impact of this initiative [134–142]. The RE-AIM model has been successfully used to disseminate obesity, physical activity and healthy lifestyle programs [143–148], and is viewed as a proactive approach to translate research into communities.

Acknowledgements

The authors would like to thank the Alabama Department of Early Childhood Education, Diana Tullier, Lucy Cohen, Dr. Julie Preskitt, Dr. Kimberly Sharkins, and the Home Instruction for Parents of Preschool Youngsters Program for their support.

Funding Statement

This work was funded by the NIH/NIMHD *Obesity Health Disparities Research Center (OHDRC)* (U54MD000502) Project 2 awarded to Drs. Sarah-Jeanne Salvy and Gareth Dutton. The funding agency is not involved in the design, data collection, analysis, interpretation or writing.

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Figure 1.
Enrollment flow

Table 1.

Logic Model of HABITS

Situation: Low-income and racial/ethnic minority mothers[1] and their young children[43–46] are especially at-risk for obesity and related diseases, and the lack of access to evidence-based obesity efforts further contributes to these disparities.		
Inputs	Outputs	Outcomes
<ul style="list-style-type: none"> • Existing maternal-child health infrastructure • Funding • Input from childhood obesity experts • Provision of health services (obesity intervention) • Partnership between academia and maternal-child services 	<p>Activities</p> <ul style="list-style-type: none"> • Implementation of a targeted obesity intervention based on habit-formation and choice architecture of personal and household environment • Focus on mother-child health behaviors, interactions and norms <p>Participants</p> <ul style="list-style-type: none"> • Sociodemographic: underserved, low-income, predominantly African American mother-children enrolled in home visitation services • Home visitation directors, staff and stakeholders 	<p>Short and Medium Term</p> <ul style="list-style-type: none"> • Increased access to obesity intervention • Increase mothers' health literacy and empowerment over their personal and home environment • Improved mother and child health behaviors and weight <p>Long-term</p> <ul style="list-style-type: none"> • Decrease obesity and health disparities among underserved low-income mothers and children and reduce costs
<p>ASSUMPTIONS</p> <ul style="list-style-type: none"> • Conventional lifestyle programs often aimed at too many complex components that are too distal from the primary target (weight) to produce lasting changes. • Sustained and repeated behavioral practice with corrective feedback is necessary to promote mastery and maintenance of healthy habits. • Environmental cues can either support or interfere with healthy habits, and they need to be explicitly addressed through in the home environment to promote habit-formation. 		<p>EXTERNAL FACTORS</p> <ul style="list-style-type: none"> • Modifying the food environment at the population level is a complex and long-term undertaking that requires changes in multiple systems of influence. Helping mothers modify their personal and household environments is more immediately feasible and empowering. • Home visitation programs provide a scalable, sustainable, cost-effective delivery model for obesity interventions. • Underserved families lack access to opportunities and resources that facilitate healthy behaviors.
<p>DELIVERABLES: Scientific/academic (journals and conferences) and non-academic outlets (online media; meeting with stakeholders). The intervention material will be included in a guidebook for implementers to promote nationwide uptake and optimize the public health impact of this research.</p>		

Table 2.

Intervention components

	HIPPY	HIPPY + HABITS
Early childhood education and school readiness	X	X
Parenting	X	X
Socioemotional development	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 (mothers only)		X

Table 3.

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 [65–71].	<p>Habit formation: Mothers (with children involved) will learn to change habits around intake of fried foods: (1) identify cues/situations/triggers associated with fried food intake (e.g., certain foods such as fish, okra or chicken; fast food restaurant), (2) select alternative cooking methods or food selection (e.g., grilled or baked), (3) consistently repeat the new behavior in response to the cues until mastery and automaticity are reached. Didactic recommendations (e.g., modifying families' deep fried chicken recipe for oven-baked "fried chicken") will be supported by hands-on practice activities involving both mothers and children. Similar habits will be shaped and practiced to address food selection outside the home.</p> <p>Home environment: Mothers will be taught to change their home food environment by avoiding bringing fried foods into the home, limiting access to ingredients necessary for frying foods, and promoting access to recipes and ingredients for alternative cooking methods.</p>
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 [72–75]. Current 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.	<p>Habit formation: Mothers (with children involved) will learn to change habits around consumption of SSB: (1) identify cues/situations/triggers associated with SSB intake (e.g., meals, soothing children), (2) select an alternative beverage (e.g., water or lower-fat milk), and (3) consistently repeat the new behavior in response to the cues until mastery and automaticity are reached.</p> <p>Home environment: Mothers learn to change their beverage choice architecture by avoiding bringing SSB in the home and by storing SSB in inconvenient/inaccessible/hidden locations.</p>
Behavior #3: Increase intake of non-starchy vegetables and fruits	
The USDA guidelines recommend that preschoolers consume 1–1½ cups of raw or cooked vegetables, or 2 cups of raw leafy greens (raw or cooked; fresh, frozen, canned) and 1–1½ cup of fruits (fresh, canned, frozen, or dried) [86–88].	<p>Habit formation: Mothers (with children involved) will learn to form habits around consumption of fruits and vegetables <i>instead of energy-dense alternatives</i> (i.e., switch message): (1) identify meals and snacks as cues/situations/triggers associated with fruits and vegetables intake, (2) learn to prepare/cook/store non-starchy fruits and vegetables, and (3) consistently provide fruits and non-starchy vegetables for every snack and meal <i>instead of energy-dense foods</i>. Hands-on activities (e.g., taste tests, cooking and storing demonstrations) will promote multi-sensory exposure and increase children's acceptance of novel fruits and vegetables.</p> <p>Home environment: Mothers learn to increase the accessibility and visibility of fruits and vegetables in their home. Proper food preparation and storage (e.g., freezing) can reduce food waste of perishable items and ensure availability of fruits and vegetables throughout the month (i.e., not limited by monthly financial fluctuations)</p>
Behavior #4: Increase daily steps	
Preschoolers (3 to 5 years of age) should be physically active every day for at least 60 minutes (up to several hours), and avoid being sedentary for more than 60 minutes at a time, except when sleeping [89, 90].	<p>Habit formation: Mothers (with children involved) will learn to form habits around physical activity and active play: (1) identify child and mother specific cues/situations/triggers that will become associated with physical activity (e.g., stairs; time of day), and (2) identify specific activities that will be consistently repeated in response to daily cues (e.g., 10-min walk after breakfast; acting out movements in response to storytelling).</p> <p>Home environment: Mothers are key contributors of children's activities in providing access and opportunities. Mothers will learn to increase the availability/accessibility/visibility of physical activity cues (e.g., walking shoes, jump rope) and reminders in the home, and to optimize their use of safe spaces around the house. They will receive information on free group activities and classes they can share with their children and other families.</p>
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 [79–85].	<p>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).</p> <p>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.</p>

Table 4.**Measurements**

	Baseline/Enrollment	Post-intervention	1-year follow-up
Demographics and medical history	x		
Mother anthropometrics (height, weight, and waist circumference)	x	x	x
Child weight change	x	x	x
Home food and activity environment (<i>Home Food Assessment</i> ; HFA and <i>Home Inventory Describing Eating and Activity Development</i> ; 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