Disseminating & Implementing a Lifestyle Based Healthy Weight Program in a National Organization

Protocol

Date created (Version 4.4): July 17, 2025

TABLE OF CONTENTS

A Introduction

A1 Study Abstract

Excessive weight gain among young adult women age 18-45 years is an alarming and overlooked trend that must be addressed to reverse the epidemics of obesity and chronic disease. During this vulnerable period women tend to gain disproportionally large amounts of weight compared to men and other life periods. Our team developed a lifestyle modification intervention Healthy Eating & Active Living Taught at Home (HEALTH) that prevented weight gain, promoted sustained weight loss, and reduced waist circumference in an effectiveness trial in partnership with Parents as Teachers (PAT), a national home visiting, community based organization with significant reach in this population. PAT provides parent-child education and services free-of-charge to nearly 170,000 families through up to 25 free home visits per year until the child enters kindergarten. This study will extend our previous work to evaluate dissemination and implementation of HEALTH across three levels (mother, parent educator, PAT site) to achieve widespread impact. We will conduct a pragmatic cluster randomized controlled trial to evaluate HEALTH and the HEALTH training curriculum (implementation strategy) on weight among mothers with overweight and obesity across the US (N= 200 HEALTH; N= 200 usual care). Parent educators from 40 existing PAT sites (20 HEALTH, 20 usual care) will receive the HEALTH training curriculum through the PAT National Center, using PAT's existing training infrastructure, as a continuing education opportunity. An extensive evaluation, guided by RE-AIM, will determine implementation outcomes (acceptability, adoption, appropriateness, feasibility, fidelity, and adaptation) at the parent educator level. The Conceptual Framework for Implementation Research will characterize determinants that influence HEALTH dissemination and implementation at three levels (mother, parent educator, PAT site) to enhance external validity (reach and maintenance) and population level impact. The findings from this innovative study will have significant potential to help reverse the trend of excessive weight gain among young adult women, a critical priority target in battling the epidemics of obesity and chronic disease, by reaching women with an evidence-based intervention nation-wide.

B Primary Hypothesis

The magnitude of the between-group difference in baseline to 24-month change in weight will be at least 4.7 kg, with mothers receiving HEALTH gaining less weight than those receiving usual care.

C Background

D Prior Literature and Studies

Among women, early adulthood (18–45 years of age) is a particularly vulnerable time period, during which they tend to gain disproportionately large amounts of weight,

making prevention of weight gain an important target for obesity prevention efforts.[1-3] Maternal weight change in young adulthood, often initiated during pregnancy and maintained after the postpartum period, can impact obesity risk for the rest of a woman's life.[4-6] Data from the most recent NHANES survey show that among adult women, the prevalence of obesity in 2011-4 ranged from 12% for Non-Hispanic Asian women to 57% among Non-Hispanic Black women,[7] indicating the burden of obesity is borne disproportionately by some groups. NHANES data also demonstrated that obesity increased among women from 2005-6 to 2013-4, but not among men.[8] Secular trends toward dramatic gains, particularly in young adult women, have been observed in the few representative longitudinal studies that have been conducted.[1,3,9,10] For example, The Coronary Artery Risk Development in Young Adults (CARDIA) study enrolled young adults (18-30 years old) in 1985-6; periodic measurements through 1995-6 found 68% of white women and 78% of Black women who began the study overweight gained at least 5 kg over 10 years and 20% and 29% of these respective groups gained excessive (>20 kg) amounts of weight.[2] Reaching young mothers with interventions that can reverse the trend of excessive weight gain among young adult women is critical to battling the epidemics of obesity and chronic disease.

Dissemination and implementation (D&I) evidence-based interventions, which translate the Diabetes Prevention Program (DPP) into real-world practice, hold promise for impacting the secular trends described above, as prevention of weight gain is a priority intervention target.[3] Follow-up data from the DPP demonstrated the lifestyle intervention, targeting improved dietary intake and physical activity, decreased the incidence of diabetes by 27% over 15 years in overweight and obese adults with impaired glucose tolerance, compared to the placebo group.[11,12] Moderate weight loss can delay or decrease the risk of developing obesity related diseases, such as cardiovascular disease and diabetes,[11,13,14] and metabolic studies have found that for some outcomes, most of the improvement from a weight loss of up to 15%, come with the first 5% of weight lost.[14] Improvement in blood pressure can be achieved even with as little as 3% weight loss.[15-18] In DPP translation studies, Aziz et al. found the percentage of participants achieving a 5% weight loss ranged from 20% to 64% across interventions.[19] While interventions are able to achieve weight loss, they often ultimately result in diminished effect and weight regain over time.[12,20-27] One study found changes in chronic disease risk factors were not different between participants who lost, then regained weight compared to those who did not lose weight.[28]

Despite efforts to translate the DPP to broader populations,[29-33] evidence-based interventions often fail to reach young women, who are at high risk for weight gain.[34] Women with young children face time and childcare barriers, which impact participation, engagement, and retention; this is of concern as success in programs such as the DPP is associated with attendance.[35] Discrepancies exist between evidence-based, efficacious interventions such as the DPP, and the practical reality of what can be implemented in real-world settings.[11,36-39] This study will build on our previous work embedding core DPP elements into the usual practice of a home visiting program that already offers intensive contact over time, and extends this by using PAT's own staff and training infrastructure. This study will also assess the effectiveness of the HEALTH training curriculum (the implementation strategy) and the external validity of this approach when HEALTH is implemented in real-world sites, critical to ensuring sustained impact.

D1 Rationale for this Study

Excessive weight gain among young adult women (18-45 years) is an alarming and overlooked trend that must be addressed to reverse the epidemics of obesity and chronic disease.[3] On average, young women gain as much as 0.96 kg per year, for a total of 11.9 kg over 10 years.[2] Based on large scale epidemiologic studies,[9] gaining as little as 2.5 to 10 kg can increase a woman's risk of death from cardiovascular disease by 25%. Development of obesity during childbearing years may also lead to its intergenerational transfer, heightening the need for interventions to prevent weight gain. During this vulnerable period women tend to gain disproportionally large amounts of weight compared to men and other life periods.[1-3] Evidence-based interventions, such as the DPP,[12] often fail to reach this population due to time and priority constraints.[34] Our team developed an intervention that prevented weight gain and promoted sustained weight loss in partnership with Parents as Teachers (PAT),[40] a national home visiting, community based organization with significant reach in this population. PAT provides parent-child education free-of-charge to women and families, through up to 24 home visits per year that begin prenatally and continue until kindergarten. In 2016, 4,999 parent educators, in 3,246 sites across all 50 states, conducted >1.7 million home visits with nearly 170,000 families.[41]

D&I of an evidence-based intervention within PAT can prevent chronic diseases such as cardiovascular disease and diabetes among mothers nationwide.[11,19,42,43] Since HEALTH is embedded within PAT's existing home visits (without adding visits), which provides long-term interaction with the family (from prenatal until the last child in the home enters kindergarten),[41] it is able to provide a 'limited content + long-term delivery' approach. This approach supports mothers in making incremental changes in eating and physical activity behaviors, and prevents weight gain.[44] In an effectiveness trial, HEALTH led to a 4.7 kg weight difference between groups, reducing weight by 1.5 kg in the intervention group, relative to a 3.2 kg gain in the usual care group over 2 years.[40] Embedding HEALTH within PAT overcomes barriers to participation and reflects the United States Preventive Services Task Force (USPSTF) recommendation of 12 intervention sessions per year.[45] Mothers are already motivated to participate in PAT to benefit their child. This enables participation in HEALTH, an intervention that prevented weight gain, promoted weight loss, and reduced waist circumference (which help prevent cardiovascular disease and diabetes)[40] and is ready for D&I.

The proposed study extends our previous work with a Hybrid Type 2[46] pragmatic cluster randomized controlled trial to evaluate D&I of HEALTH across three levels (mother, parent educator, PAT site) to achieve widespread impact. First, we will determine weight outcomes among 504 overweight/obese mothers (N=200 HEALTH; N=200 usual care) when parent educators (~8/site) from 40 PAT sites nationwide (20 HEALTH, 20 usual care) receive the HEALTH training curriculum (the implementation strategy[47]) through PAT National Center's existing training infrastructure. From a D&I perspective, an evaluation guided by RE-AIM will measure implementation outcomes (acceptability, appropriateness, feasibility, fidelity, adaptation).[48-50] Further, the Conceptual Framework for Implementation Research will guide an assessment of factors that influence external validity at multiple levels (mother, parent educator, PAT site) to maximize HEALTH D&I.[51,52] This innovative study provides the evidence necessary for sustainable D&I of HEALTH across PAT's national network, promoting healthy weight and preventing chronic disease on a national scale.

E Study Objectives

E1 Primary Aim

Aim 1. Determine the effectiveness of HEALTH on weight and behaviors among 200 overweight and obese mothers when disseminated and implemented across 20 real-world PAT sites. We hypothesize:
Hypothesis 1.1 The magnitude of the between-group difference in baseline to 24-month change in weight will be at least 4.7 kg, with mothers receiving HEALTH gaining less weight than those receiving usual care. [*primary*]
Hypothesis 1.2 Mothers in HEALTH will improve dietary (e.g., reduce sugar beverages) and physical activity (e.g., increase brisk walking) behaviors over 24 months, compared to usual care. [*secondary*]
Hypothesis 1.3 Relative to usual care, mothers in HEALTH will improve the home food environment. [*secondary*]

E2 Secondary Aims

Aim 2. Evaluate the HEALTH training curriculum's impact on implementation outcomes (e.g., acceptability, fidelity), at the parent educator level, when 112 parent educators (~8/site) are trained by PAT National Center. We hypothesize that parent educators receiving the HEALTH training curriculum will:
Hypothesis 2.1 Deliver HEALTH with fidelity (adherence, quality of delivery, exposure to the intervention, and participant responsiveness or involvement). [*primary*]
Hypothesis 2.2 Deliver HEALTH as designed, but adapted for content, consistency, and intensity. [*secondary*]
Hypothesis 1.3 Rate HEALTH acceptable, appropriate, and feasible to implement in routine practice. [*secondary*]

Aim 3. Characterize determinants that influence HEALTH D&I at three levels: mother, parent educator, PAT site to enhance external validity (reach and maintenance/sustainability).
Question 3.1 Are the mothers participating in HEALTH representative of typical PAT participants?
Question 3.2 What characteristics of parent educators make them more likely to deliver HEALTH with fidelity?
Question 3.3 Are there characteristics of PAT sites that make them more likely to adopt and maintain HEALTH?

E3 Rationale for the Selection of Outcome Measures

Weight change was selected as the main outcome measure as the aim of the study is prevention of weight gain.

F Investigational Agent

F1 Preliminary study

In the efficacy study (NIDDK grant no. R18DK089461; registered at www.clinicaltrials.gov NCT01567033.), women in the usual care versus intervention group were significantly less likely to achieve 5% weight loss at 24 months (11% vs 26%, p=0.01). At 12 months, there was a 2.8-kg difference in weight between groups (p=0.0006), and by 24 months a 4.7-kg difference in weight (3.2 [SD=7.6] kg vs –1.5 [SD=8.3] kg, p=0.002); group differences in waist circumference were also evident by 12 months (2.1 [SD=8.4] cm vs –0.7 [SD=9.8] cm, p=0.04) and 24 months (3.8 [SD=10.6] cm vs –2.5 [SD=9.1] cm, p=0.005), as were improvements in behavioral outcomes. There was no difference in blood pressure between groups.[53]

G Study Design

G1 Overview or Design Summary

The study includes a Hybrid Type 2 (efficacy/implementation) cluster randomized trial. Since parent educators from each PAT site will be trained together (risk for contamination) and several research questions relate to the PAT site level, a cluster randomized trial is appropriate.[54-56] PAT National Center will train educators affiliated with 40 PAT sites in HEALTH; among these, 20 will be randomly assigned to receive the HEALTH training curriculum (implementation strategy), and 20 will serve as controls, delivering usual care PAT. Given the multi-level nature of this study, there are two types of participants: 1) mothers and 2) PAT staff

1.a Inclusion Criteria

PAT sites: Sites will be selected from the pool of 3,246 sites to be among the 40 included in the trial then randomized. To be eligible, sites must report seeing 25 families per year, to assure the required number of mothers per site will be able to be recruited during the study period. Further, to avoid compromising at PAT site's ability to complete its primary function of delivering PAT by imposing the burden of a study, only sites in compliance with the PAT model are eligible.

Mothers: As a pragmatic trial, it is important that study participants closely match the usual case load for PAT; inclusion criteria have been selected accordingly.[57] For inclusion in the analytic sample, participants must be 18-45 years of age, overweight or obese (BMI 25-45 kg/m^2), English or Spanish speaking, participating or willing to participate in PAT at a participating PAT site for 2 years, and able to give informed consent for participation.

PAT staff: All parent educators at sites participating in the study will be invited to participate. If parent educators elect not to receive the HEALTH training curriculum (the implementation strategy), they will still be allowed to consent to the study and participate in the survey; if they decline to consent to the study and participate in the survey, educators will still be allowed to receive the training; however, mothers on these educators' case loads will not be eligible for the study.

1.a Exclusion Criteria

Mothers: Women who are currently pregnant, fewer than 6-months postpartum, or planning to become pregnant in the next 24 months; are unable to speak English or Spanish; and/or are unable to engage in a walking program will be excluded.

PAT staff: at least 18 years of age

1.b Participant Recruitment Plans and Consent Process

Mothers: Our plan to recruit participants mirrors routine PAT 'rolling' recruitment throughout the year. Parent educators may provide study fliers or emails to families (parent educators commonly provide materials to families). If the PAT site is hosting an event at which study consent might occur and measures might be taken, parent educators might provide flyers or emails about these events as well. Interested families will either call the number on the flyer or indicate their interest to the parent educator; the parent educator will send the names of mothers who express interest in additional information to the research team who will coordinate an outreach/screening call or text. Screening and data collection procedures will be will be conducted with a data collector. Data collectors could be a local study team member who calls from (for screening calls) and/or travels from St. Louis (for in person screening and/or measurement) to the site or an individual hired locally to complete data collection. Data collectors will screen potential participants by phone or at site events to ascertain self-reported height and weight, to determine eligibility. If eligible based on self-report, the data collector will consent the participant to a baseline visit and schedule this baseline visit. At the baseline visit, the informed consent process will occur before baseline data collection, with the data collector. These visits may occur in the woman's home, some other location she prefers (e.g., library, doctor's office, PAT site), or at PAT site events. As data collection will occur electronically, the participant will have the opportunity to review the consent information on the electronic data collection device (i.e., tablet) before initiating data collection and receive a paper copy of the document, however, we have requested a waiver of documentation of consent. The data collector will also measure height and weight to confirm eligibility based on BMI. Those found to be ineligible and those not providing consent will continue with PAT visits, but will not be part of the study (will not participate in any study measures). To minimize the possibility of coercion or undue influence during the consent process, mothers will have as much time as needed to decide about participation, and the data collector will remind them that their PAT services will not be affected by their decision to participate or not.

PAT staff: When a site agrees to participate in the study, all parent educators will be made aware of the opportunity to participate in the study through a flyer and/or email message and/or announcement at a staff meeting or training. If the parent educator is interested in participating, they will contact the research team by email. Site leaders may also provide a list of educators along with their contact information. The research team will reach out to parent educators by phone and email to conduct informed consent and send the information sheet by email. To minimize the possibility of coercion or undue influence during the consent process, parent educators will have as much time as needed to decide about participation, and the research team will remind them that participating will not affect their employment.

1.c Randomization Method

PAT sites will be randomly assigned to HEALTH or usual care via a dynamic randomization scheme,[58] in which percent of low-income and number of families served will be considered so that we achieve similar distributions in both arms of the study. The first 12 sites will be randomized to HEALTH or usual care arms in a 1:1 ratio within five site pairs where two sites are matched closely on total size and percent of low-income families. There are two sites that cannot be matched; for these two sites, several possible randomizations will be elicited in a 1:1 ratio and the randomization that best maintains the overall balance (on total size and percent of low income families) between the two treatment groups will be selected. Subsequent sites will use a dynamic randomization scheme, the details of which will be determined when those sites are recruited. Again, they will be randomized to best maintain the overall balance (on total size and percent of low-income families) between the two treatment groups.

1.d Early Withdrawal of Participants

Mothers: Participants who decide they would no longer like to participate in the study are free to withdraw at any time; they may continue with PAT visits, but will not be part of the study (will not participate in any study measures).

PAT staff: Participants who decide they would no longer like to participate in the study are free to withdraw at any time; this will not affect their employment, but they will not be part of the study (will not participate in any study measures).

1.e When and How to Withdraw Participants

Should a participant (mother or PAT staff) wish to withdraw from the study, they can do so at any time by completing the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu (or use this link: https://hrpo.wustl.edu/participants/withdrawing-from-a-study/) or requesting that the Investigator send a copy of the letter.

1.f Data Collection and Follow-up for Withdrawn Participants

Participants (mother or PAT staff) who decide to withdraw will not participate in any additional measurement or follow-up.

G2 Description of usual care PAT and HEALTH interventions

2.a Description

Given the national scale of PAT and the considerable variability between sites and participants, PAT curricula are primarily hands on, including dynamic interactions and role-playing. This allows for adaptation at the level of the mother-parent educator relationship, where the parent educator is able to tailor the program to meet the mother's context.[49,59] Section 2.d provides additional detail.

2.b Usual care description

Participants at usual care PAT sites will receive the Foundational (usual care) curriculum that uses a strength-based, solution-focused model.[60] It includes 60-minute home visit plans[60] that focus on 1) rapport building (e.g., reflective questions to get to know the family such as “What did you notice about your child’s development?”), 2) development-centered parenting (e.g., comparing and ordering for math skills), 3) parent-child interaction (e.g., measuring dried beans), 4) family well-being (e.g., address needs in the family’s physical and emotional environment such as “Who do you think supports your child to be happy and successful?”), and 5) closing/reinforcement and follow-up plans (e.g., feedback on goals, praise for success). The frequency and number of visits are based on the family’s needs and preferences.

2.c HEALTH description

Participants at HEALTH (intervention) sites receive the Foundational curriculum + evidence-based lifestyle change strategies to prevent weight gain and promote weight loss embedded within and delivered as part of home visits. The HEALTH intervention is guided by PAT’s strength-based, solution-focused model and a socio-ecologic approach recognizing the protective and interactive influences on women across multiple levels.[61,62]

A detailed sample of the curricular materials unique to the HEALTH intervention are included in Appendix A. In addition to the usual care PAT curriculum content, goal setting related to healthy weight, and the importance of parental modeling of healthy eating and physical activity are incorporated throughout the discussion and visit. Content mirrors the structure of the Foundational curriculum described above, but is enhanced to embed lifestyle change as the following example illustrates: 1) rapport building (e.g., reflective questions to get to know the family such as “What did you notice about your child’s development + What did you notice about your families eating?”), 2) development-centered parenting (e.g., comparing and ordering for math skills + healthy portion size), 3) parent-child interaction (e.g., measuring food in appropriate portion size), 4) family well-being (e.g., address needs in family’s physical and emotional environment such as “Who do you think supports your child to be happy and successful? + What could you do at home to make it easier to eat healthier portions?”), and 5) closing/reinforcement and follow-up plans (e.g., feedback on goals, praise for success). Other objectives include skill building and strategies to address: reduction of high-sugar beverages, substituting healthy for unhealthy foods, portion control, and eating patterns. Physical activity goals encourage a total of 150 minutes (2.5 hours) of moderate-intensity exercise (e.g., brisk walking) and/or lifestyle activity per week.[63] HEALTH participants will be provided pedometers, allowing them to track and self-monitor their steps.

2.d HEALTH dose

Intervention dose. HEALTH may be delivered over 24 months via a (1) core and (2) maintenance phase. Modeled after the Diabetes Prevention Program (DPP)[11,12,25] and various effective DPP adaptations,[31,33] the visits begin with greater frequency, and

taper. HEALTH was effective with families receiving, on average, 23 visits over two years, with 39% of families receiving <15 visits, 36% of families receiving ≥25 visits, and 15% receiving >30. Consistent with PAT practice, the frequency and number of visits are determined by the family's needs and preferences, therefore the dose structure for HEALTH is flexible. A sample number of visits is provided in *Table 1*, but will likely differ by family (as was the case in the effectiveness trial) so that each family gets what they need in terms of content, number of visits, and visit frequency. The core phase (months 1-6) is the most intense and structured phase, delivered via ~13 home visits. During this phase, participants are taught basic information about healthy eating and physical activity and are given the opportunity to practice related behavioral skills during home visits (*see lesson topics and examples in Table 1*). During this time the parent educators and mothers learn how to best work together to achieve study goals. The maintenance phase (months 7-24) reinforces lessons learned in the core phase while assisting participants in focusing on issues of relevance and problem-solving via 10 home visits. As PAT is designed to be a universal program,[44] HEALTH was also designed to be universal; for example, while the HEALTH program stresses reducing sugar-sweetened beverage intake, parent educators tailor this to the specific types of beverages women in different cultures drink (e.g., sodas, Kool-Aid, Agua Fresca, orangeade).

2.e HEALTH training curriculum (implementation strategy)

We will use PAT's existing infrastructure to deliver our implementation strategy, the HEALTH training curriculum.[47] This includes:

Training materials used in the HEALTH effectiveness trial and developed with the input of PAT National Center, will be formulated into the type of curriculum manual PAT parent educators are accustomed to receiving.

PAT parent educators will be trained to deliver HEALTH through a specialty training delivered by PAT National Center. In preparation for the current proposal, we worked with PAT National Center to harmonize the HEALTH training curriculum with the organization's usual practice and training infrastructure. The protocol may be delivered through an interactive training that includes seven components: 1) HEALTH background and rationale, 2) guidelines for healthy weight behaviors, 3) overview of the HEALTH protocol, 4) the importance of the mother's lifestyle and influence on child weight and development, 5) role-play practice sessions with other parent educators, 6) instruction on the use of self-monitoring tools and 7) feedback from trainers. Consistent with PAT training protocols we have successfully implemented,[64-66] HEALTH educators must complete a posttest reflecting training objectives. A pretest will be available to frame training. Trainees must receive ≥90% correct on the posttest before delivering the intervention to participants.

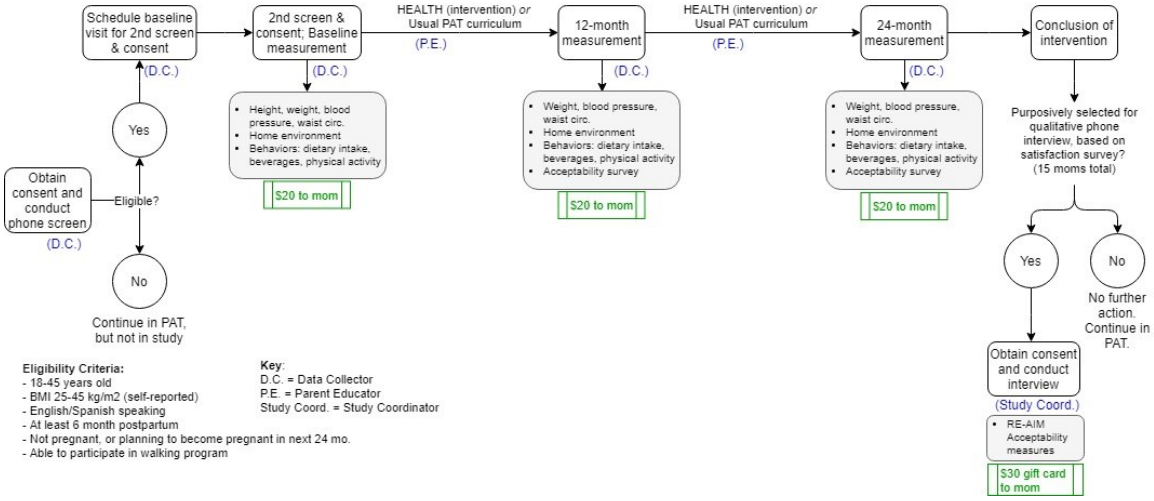
Ongoing consultation will include 'booster' sessions, consistent with PAT 'communities of practice'. PAT educators may receive training and supervision by the research coordinator (dietitian and PAT parent educator) and by a parent educator with experience in similar trials. Parent educators may receive continuing education credits (required by PAT for all parent educators) for participating in the HEALTH training curriculum.

H Study Procedures

H1 Screening for Eligibility

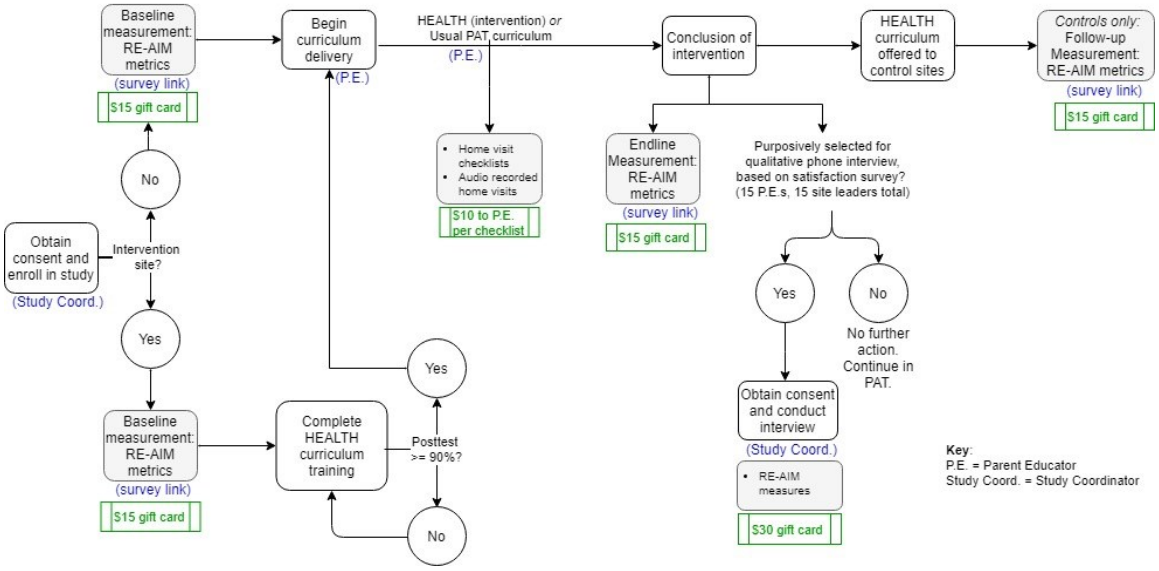
Mothers: Screening for mothers will occur in two phases. First, data collectors (study team members) will screen potential participants by phone to ascertain self-reported height and weight, to determine eligibility. If the mother is eligible based on this screening, they will be offered a baseline visit. These visits may occur in the woman's home, some other location she prefers (e.g., library, doctor's office, PAT site), or at PAT site. At this visit, the data collector will assess height and weight to assure the mother's BMI is within the eligibility range. The procedures for these participants are outlined in Figure 1. Given in-person procedures are not possible during COVID-19 physical distancing, alternate procedures are outlined in Appendix C.

Figure 1. HEALTH D&I Measurement: Participants (Intervention and Usual care)



PAT staff: as there are no exclusion criteria, no screening is required. The procedures for these participants are outlined in Figure 2.

Figure 2. HEALTH D&I Measurement: Parent Educators & Site Leaders (Intervention and Usual Care)



H2 Schedule of Measurements

Mothers: The flow of participants is outlined in Figure 1. After the mother consents to study participation, the data collector will conduct baseline measures (i.e., anthropometry, blood pressure, behavior measures, home environment measures); data collection is summarized in Table 1 (below). Data collectors will conduct anthropometry and blood pressure measures and mothers will be asked to complete surveys for data collection. Data collection will occur again at 12 and 24 months (conducted by the data collector at all time points). As randomization will be at the PAT site level, data collection will be the same for both HEALTH and usual care with one exception. Mothers will be asked to complete an acceptability survey along with their 12 and 24 month measures. Given in-person procedures are not possible during COVID-19 physical distancing, alternate procedures are outlined in Appendix C.

During home visits, parent educators may (with participant consent) record the visits so that fidelity to and adaptations from the intervention can be monitored.

Table 1. Summary of Measures

	Acronym	SC	BL	M12	M24
Time point					
Day (window, ± days from randomization)			≤180		
Day (window, ± weeks from BL)				365±90	730±90
MOTHER-LEVEL DATA					
Telephone Screening (self-report HT, WT → consent)		●			
Demographic and Socio-Economic Characteristics	DEM		●		
Anthropometrics					
Height	HT		●		
Weight	WT		●	●	●
Blood Pressure	BP		●	●	●
Waist Circumference	WC		●	●	●
Safety monitoring (excessive weight loss - >15%)				●	●
Behavior					
NHANES Dietary Screener Questionnaire (from			●	●	●

HEALTH)					
IPAQ (http://uacc.arizona.edu/sites/default/files/ipaq_english_telephone_short.pdf)			•	•	•
Home Environment					
Kegler_2014_The influence of home food environments on eating behaviors of overweight and obese women			•	•	•
HEALTH Effectiveness Trial Items (SES, race/ethnicity, norms)			•	•	•
Individual Parent-Level Satisfaction Measure (RE-AIM measure: acceptability)				•	
Testing performed by the data collectors; respondent self report					

Mothers in the HEALTH group will be purposively selected to be representative of those with varying (high, middle, low) scores on the quantitative measures for acceptability (acceptability survey). Interviews will be completed by phone, and will be digitally recorded. We anticipate interviews to assess implementation outcomes (acceptability, appropriateness, and feasibility) will last 45-60 minutes.

Mothers will receive PAT services throughout the 24 months, consistent with PAT practice; mothers served by sites randomized to HEALTH will receive PAT from parent educators trained in the HEALTH curriculum, and those served by usual care PAT sites will receive usual care PAT. Once final data collection occurs at 24 months, no additional follow-up will occur.

PAT staff: The flow of participants is outlined in Figure 2. After PAT staff consent, those at sites randomized to HEALTH may be trained in the HEALTH training curriculum through PAT's existing training infrastructure. Staff at sites randomized to usual care will continue to provide usual care PAT, and will be able to receive the HEALTH training curriculum at the end of the study. Staff at both sites will be asked to record visits with study participants so that fidelity to and adaptations from the intervention can be monitored and to complete visit checklists after each visit with a participating mother documenting visit content.

Staff at all sites will be asked to complete surveys to assess implementation outcomes (acceptability, adoption, appropriateness, feasibility, fidelity, and adaptation). Staff at sites randomized to the HEALTH training curriculum will be asked to take the surveys at enrollment/randomization (before training) and again after training. Parent educators in usual care sites will also be asked to complete the measures at baseline, upon enrollment into the study. Both sets of educators will be asked to complete the measures at the end of the intervention period, before the usual care sites receive the HEALTH training curriculum. Usual care parent educators will complete a final round of surveys after they receive the HEALTH training curriculum.

PAT staff will be purposively selected to be representative of those with varying (high, middle, low) scores on the quantitative measures for acceptability to be invited to participate in qualitative data collection. Interviews will be completed by phone and will be digitally recorded. We anticipate interviews to assess implementation outcomes (acceptability, appropriateness, and feasibility) will last 45-60 minutes. Parent educators will complete interviews after conducting HEALTH with at least three families. Following this final data collection, no additional follow-up will occur.

I SAFETY MONITORING

The study will monitor participant safety. One aspect of this monitoring is to evaluate potential participants at screening to determine whether it is safe for them to participate in the interventions.

I1 Potential Risks

This study is minimal risk as defined by 45 CFR 46.102: “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”. Therefore, we anticipate no psychological, social or legal risks beyond those of participation in minimal-risk research in general.

Participants may find some of the questions in the questionnaire assessments embarrassing. They may be uncomfortable having their height, weight, waist circumference, and blood pressure measured.

A potential risk to study participants is loss of confidentiality.

I2 Surveillance and Reporting Procedures

This study does not involve a drug intervention, device intervention, or highly invasive data collection procedure. However, recognizing that unanticipated events can occur in the course of any study, even a minimal risk study, the following reporting protocols will apply.

This study will collect the following information for events that occur during the conduct of study activities (i.e., collection of study data or home visits):

- unanticipated (i.e., unexpected) and related adverse events (possibly related or definitely related to study participation) and
- unanticipated problems that may involve risk to participants or study staff, but do not necessarily result in an adverse event (i.e., harm).

These will be monitored using two mechanisms:

1. Events (Possible AEs) observed (e.g., discomfort with measures, elevated blood pressure) by members of the study team (i.e., data collectors or parent educators) will be reported directly to the project coordinator. Team members will report a detailed description of the possible adverse event including the participant ID number, who reported the event to HEALTH staff; who witnessed the event; when, where, how the event occurred; and any action taken in response. The information will be conveyed by email. The project coordinator, in collaboration with the PI will (1) determine if the event qualifies as an AE, (2) follow-up as appropriate, and (3) report AEs in the REDCap database (the following will be reported in the REDCap database for AEs: AE description with

dates, actions taken in response, and event classifications including final status, expectedness, relatedness, and severity) and to the IRB/DSMB (as appropriate).

2. Weight will be annually monitored as mothers are weighed at 12 and 24 months to be sure that weight loss is not excessive. Should a mother lose greater than 15% body weight over a 12 month period a member of the study team or PI will reach out to the participant and administer Eating disorder Screen for Primary care [ESP], a screening for eating disorder. Appropriate referral will be made if the screen is positive. In addition, those that gain over 15% body weight over a 12 month period a member of the study team or PI will reach out to the participant to refer her to her health care professional.

Mothers who become ineligible over the course of the study (i.e., due to pregnancy) will be withdrawn from the study.

I3 Safety Monitoring Plan

A Data Safety and Monitoring Board (DSMB) will oversee study implementation. Further details on the Data Safety and Monitoring Plan and the Data Safety Monitoring Board are located in Appendix B.

J Statistical Plan

J1 Sample Size Determination and Power

We are confident the tabulated computations that led to our decision to randomize 40 sites (20 to each arm) are, if anything, conservative. Tabulations are based on weight at 24 months as the primary outcome and are for two-sided tests at the 0.05 significance level.

Table 2: Number of subjects required in each PAT site for two-sided tests at the 0.05 level of significance.

# PAT sites per group	Power	Between group difference	Intraclass correlation coefficient		
			0.01	0.02	0.05
19	0.8	4	6	6	7
	0.9	4	8	8	11

The table entries (Table 2, above) are the required sample size per cluster completing data collection for power values of .8 and .9; for ICC values of .01, .02, .and 05; for 19 PAT sites per group, and for between group differences of 4 between-group difference in the baseline to 24-month change in body weight that can be detected. Prior data from the HEALTH effectiveness trial found the standard deviation of the change in weight from baseline to 24 months was 8.3 kg. To be conservative, the computations assume an increased value of 10 for the standard deviation. The computations also assume 7 mother will complete 24 months of follow-up at each of 19 PAT sites. The number actually enrolled will be increased to 10 mothers (to account for a potential dropout rate of 30%) and 40 sites (20 per arm). Based on the above parameter assumptions, Table 3 indicates that to achieve a power of 0.8 with 19 PAT sites per group and an intraclass correlation coefficient as high as 0.05, the between-group difference in the change in weight from baseline to 24 months would have to be 4. Since the HEALTH study saw a 24-month decrease in weight of 1.5 (+/- 8.3) kg in the intervention group and a 24-month increase of 3.2 (+/-7.6) kg in the control, we are confident the target of 19 PAT sites per group with 7 mothers providing 24-month data is sufficient. We emphasize these computations are conservative because they allow for more variability (i.e., assume a larger standard deviation) than was observed in HEALTH, and because our analysis will add power by including data on the dropouts who do not provide 24-month data but who do provide data at 12 months.

J2 Interim Monitoring and Early Stopping

Data from the study will be monitored on a continuous basis by the PI and research team. The PI, along with the research team. The PI and all Co-I's and research coordinators will meet every 3 months or as needed to review progress and issues. All serious adverse events (SAEs), adverse events (AEs), and anthropometric values will be reviewed by the investigators on an ongoing basis.

The Data and Safety Monitoring Board (DSMB) will have overall responsibility for monitoring the emerging results. The focus of the DSMB will be on safety issues, recruitment, retention, protocol adherence and data quality and timeliness. The DSMB will meet at least twice each year and more frequently if needed.

We have no outcome-based rules for participant termination (i.e., no participant will be terminated simply based on poor response to the intervention). The only anticipated circumstances under which a participant would be terminated from study participation would be if we, or the NIH or DSMB, determine that it would not be safe for the participant to continue. In addition, per IRB requirement, participants may withdraw from the study early if they decide they are no longer interested in participating.

J3 Statistical Methods

Initial analyses will use t-tests and chi-square tests to compare baseline characteristics across groups. If continuous variables do not satisfy the normality or equal variance assumptions of the t-tests, we will explore data transformations and, if appropriate transformations cannot be identified, may employ Wilcoxon's test.

The primary analysis outcome, weight change between visits, was compared between intervention groups using a linear mixed-effect model with repeated measures. The model included a fixed effect for intervention group, time point, and the intervention

by time point interaction with a random effect for participants nested within site In addition, we may employ models that adjust for covariates (e.g., income), if these are not balanced by randomization. The covariance structure will be determined after evaluating correlation coefficients across time and assessing both Akaike's Information Criterion and Bayesian information Criterion.

Secondary continuous outcomes will be analyzed with the same mixed-effect model. If model assumptions of normality are violated, data will be rank-transformed prior to analysis. The secondary binary outcome will be assessed using a binomial generalized estimating equation (GEE) model repeated measures, while secondary ordinal outcome (physical activity category) will be analyzed using a multinomial GEE model with repeated measures. Due to the multiple comparisons, only the primary endpoint—weight change from baseline to 24 months—will be reported as an unadjusted comparison. All other p-values will be adjusted for multiple comparisons using the Benjamini-Hochberg linear step-up procedure to control the false discovery rate across comparisons. Participants with missing data for all outcomes after baseline were excluded. Participants with at least one follow-up measurement (i.e., 12-month, 24-month, or both) were included in the analyses.

Mixed-effect analyses will also be conducted for subgroups. A per protocol analysis will also be conducted for participants completing at least four home visits . Least squares means with 95% confidence intervals will be report for changes from baseline. No adjustment for multiplicity will be applied to the confidence interval widths.

J4 Qualitative Methods

The digital recordings from interviews will be transcribed. Two researchers will analyze the transcripts. For the adaptation analysis, coding will be guided by the work of Wiltsey Stirman et al.[59,68] using a combination of deductive and emergent coding.[69] For all other analyses, after reviewing the research questions,[70,71] team members will read five transcripts using the first draft of a codebook. Each coder will systematically review the data and organize each statement into categories that summarize the concept or meaning.[72] Once these transcripts are coded, they will be discussed to ensure accuracy of the codebook and inter-coder consistency. The codebook will be edited as needed prior to coding the remaining transcripts. All transcripts will be analyzed by two coders in NVivo11.[73] Themes from coded transcripts will be summarized and highlighted with exemplary quotes.

J5 Missing Outcome Data

Missing values will be examined carefully to determine their causes and potential impact on subsequent analyses. We will evaluate whether data are missing at random. For data that are missing at random, we will conduct some analyses involving mixed models. In these analyses, missing values are dealt with in a natural manner, in that existing values are analyzed, and no observations are deleted due to missing values. In addition, we will conduct analyses where we do multiple imputation of missing values in a way that biases towards the null. Finally, we will conduct sensitivity analyses which assume that data are missing at random, to see how this impacts our results. Loss to follow up and missing and incomplete data will be monitored closely by the DSMB, to solve potential issues of missing data before there is a substantial impact on the results. For data collected as responses to questionnaires, all forms will be reviewed for

completeness before the participant leaves the study visit. Data entry will be accomplished quickly so that missing values may still be retrieved.

Under intention-to-treat principles, all participants will be included in the analysis. Where appropriate, analyses involving mixed models may be used such that all existing values are analyzed, and no observations are deleted due to missing values. Sensitivity analyses under various assumptions regarding the missing data will be conducted to confirm the robustness of the results.

K Data Handling and Record Keeping

K1 Confidentiality and Security

Data collected during measurement visits (using a tablet) will be collected using REDCap, a mature, secure web application for building and managing online surveys and databases (http://projectredcap.org/), using data entry screens developed by the statistical data analyst that include range checks (e.g., to warn the user if continuous variables are outside the range). Data collection directly into an online survey or a tablet mobile application will reduce errors in transferring data from paper to computer. Random checks of data collection activities will assure reliability. We will also include bivariate checks (e.g., weight for height).

All data will be maintained in the strictest confidence. Electronic data will be held in secure format in password-protected computer records. Data will be identified only by study number. A log of study number and identifying data and hard copy will be kept by the investigators in a locked file cabinet or secure electronic folder.

All data will be treated confidentially, and the participants' names and identities will not be disclosed in any published reports. Data security will be maintained using password protection and the standard two-key requirement of HIPAA. The automated backup procedures of our Division of Biostatistics will ensure no data is lost.

K2 Training

All study team members will receive training in proper conduct of human subjects research. For data collectors conducting screening and measuring outcome data, the study team will conduct training on study procedures. Training will include methods for screening potential participants for eligibility, securing and verifying informed consent, and completing on-site assessments of anthropometrics, blood pressure, and surveys. Depending on the number of families served by the PAT site the previous year, we may hire 1-3 data collectors near each site. To ensure accuracy and appropriate inter-assessor agreement, multiple data collectors hired per site may complete duplicate measures on practice individuals.

Parent educators at sites randomized to HEALTH will also complete human subjects training. They will review materials provided by the Human Research Protection Office and complete the required quizzes, which will be returned to the research coordinator; she will then provide the results to the Human Research Protection Office for inclusion of the parent educator as a study team member.

K3 Performance Monitoring

An important outcome of the study is to monitor parent educator fidelity to the HEALTH intervention. Careful fidelity monitoring through evaluation of visit audio recordings and visit checklists will be conducted.

L Study Administration

L1 Committees

Oversite for the study will include a Data and Safety Monitoring Board (DSMB). A chairperson and three members have agreed to serve on the DSMB, and a draft charter has been drafted. Before the study can begin, the protocol must be approved by the committee. Any subsequent major changes to a study's protocol must also be approved by the DSMB Chair.

The focus of the DSMB will be to assure that the safety of research participants is appropriately monitored and the validity and integrity of the data are ensured. The DSMB will meet at least twice each year and more frequently if needed (to be defined in the charter). Recommendations by the committee can include protocol modification or early termination for unexpected safety problems. Recommendations are made to the PI and disseminated to the NHLBI and IRB.

L2 Participant Stipends or Payments

There are several types of incentives in the study. Participating mothers will receive $20 for each research visit (baseline, 12-months, and 24-months). As the visit checklists are extra reporting for research purposes, parent educators (HEALTH and usual care) may receive $10 incentives for each visit checklist completed. Parent educators participating in surveys about implementation outcomes and context may receive $30 gift cards at each time-point. Mothers, parent educators, and site leaders participating in qualitative interviews may receive $30 incentives.

L3 Study Timetable

After initial study set-up (*Table 3*), the collaborative planning phase, IRB approval, and site recruitment and randomization (during August to December 2018), we will begin delivering the HEALTH training curriculum to sites randomized to the HEALTH arm between December 2018 and February 2019. We will begin recruiting mothers in February 2019. With a rolling recruitment, we anticipate recruitment will continue until year 3. This schedule will allow adequate time to finalize analysis, write manuscripts, and disseminate our findings.

Table 3. Study Timeline	Year 1		Year 2		Year 3		Year 4		Year 5	
Coordination, collaboration, and planning with PAT National Center	X	X	X	X	X	X	X	X	X	X
Initial site recruitment, data collector training	X									
Parent educators at HEALTH sites receive HEALTH Training Curriculum		X								
Recruitment of families		X	X	X						
Baseline Measurement		X	X	X						
Ongoing HEALTH implementation		X	X	X	X	X	X			
12-month measurement				X	X					
24-month measurement						X	X	X		
Parent educators at Usual Care Sites receive HEALTH Training Curriculum									X	
Data analysis, reporting, and dissemination of findings									X	X
Sustainability coordination with PAT National Center										X

M Attachments

M1 Appendix A. Sample of Healthy Eating & Active Living Taught at Home (HEALTH) Curricular Materials

Each visit will include review of previous topic and goal setting

	HEALTH Topic	Intent	Prompts/questions
Core Visits (1st 4-6 months - ideally every visit with family)	1. Welcome to HEALTH and goal setting)	Welcome to HEALTH. Establish rapport and discuss the benefits of participation. Provide an opportunity to set HEALTH goal(s) by using the SMART method.	Why did you want to participate in this study? What are your thoughts about health or being healthy? What do you want to learn or hope to learn about being healthy? Have you set any goals for yourself? Are you willing to set any goals during your time of participation?
	2. Healthy beverages	Build skills in reading labels to discuss sugar content and calories in various beverages. Explore the effects of sugary drinks on health. Assist parents in discovering tips to drink more water.	When you are thirsty, what do you drink? What are your favorite drinks? Do you ever drink water? If so, how much? How often? Do you know how many grams of sugar are recommended for our daily consumption? How many teaspoons of sugar are in a 20oz soda?
	3. Being active: a way of life	Make the connections between physical activity and healthy living. Identify barriers to being active. Brainstorm ways to be active.	What are your thoughts about being active? Is there anything that makes it hard for you to be active? Tell me about any activity that you do. What about activities for your children? Do you track your steps? If so, how do track your steps or what do you use?
	4. Self-monitoring	Explore the topic of self-monitoring. Increase parent's awareness of their actions and how to track their behaviors.	Have you ever tracked what you have eaten or drank? If so, why? Do you track your weight? If so, how often? How do you feel about tracking yourself?
	5. Portion Size	Discuss components of my plate. Learn recommendations for appropriate portions. Build skills in choosing healthy portions.	What size plates do you use during meals? When it is time to eat, who puts the food on the plates and how do they decide how much? What do meals usually consist of? (protein, starch, veg, etc.) When someone wants more food, what happens?
	6. Cope with triggers	Provide an opportunity to learn about food cues and ways to change them.	What makes you want to eat? How often do you eat? How can you make changes to things around your home to make it easier for your family to eat healthier?
	7. Eat well away	Assist parents in developing basic principles for	What places do you frequent when you eat away from home?

	from home	healthy eating out. Practice how to apply these principles at the type of restaurant the participant frequents.	How often do you eat fast food? (daily, weekly, etc.) If you eat out, are there ways to make healthier choices?
	8. Meal planning	Provide an opportunity for parents to brainstorm meals that their family eats. Identify ways to make the meals healthier. Practice planning and charting the meals.	How does your family decide what to eat at a meal? Are there things that make it hard to plan meals? If you are able to plan a meal, what makes that work for you? Are you able to make a meal out of the essential foods you have at home?
Follow up Visits (at least monthly)	9. Cook More	Make the connection between cooking at home and improving one's own health. Discuss practical tips to encourage more cooking at home. Explore low calorie options to favorite menus/recipes.	How do you feel about cooking? Do you cook at home? If so, how often do you cook? Does anything prohibit you from cooking? What are the kid(s) doing when you are cooking? What changes can you make in order to prepare healthier foods at home?
	10. Healthy snacking	Begin to learn appropriate portions by exploring nutrition label for common foods. Build skills in measuring out appropriate portions of food. Discuss healthy snack options.	What do you consider a snack? Do you snack? If so, how often do you snack? What snacks do you give your children? Where do you eat your snacks? Can we look at a typical food that you consider a snack?
	11. Family Meals	Learn the benefits of eating meals as a family unit. Discuss strategies to eat meals together. Plan and coordinate family meals without distractions (TV).	How do you feel about sitting down to eat together as a family? Where do you eat meals? Who is present for meals? Are there any distractions while eating?
	12. Ways to eat less calories	Identify ways to reduce calories. Discuss strategies to better eating. Develop goals for high calorie food to be changed.	What are some foods that you think are problematic? Why do you feel these are problematic? What do you think of when you hear the word calories? Are you aware of your caloric intake or do you count calories daily? Are you capable of making healthy food choices?
	13. Find time for fitness	Provide an opportunity for parents to identify positive cues to be active at home.	How do you find time to be active? How much time are you active? What can you do at home to be active? What type of activities do you do with your kids?

	14. Problem solving	Learn the steps to problem solving. Discuss barriers to making changes. Practice the steps to problem solving.	What problems have you encountered while striving to be healthy? What issue do you want to problem solve?
	15. Get support	Explore examples of problematic social cues and helpful social cues. Identify strategies for coping with social events – parties, vacations, holidays, etc.	When you are working towards your goal how do other people effect your progress? What are the positives and what makes it hard? How can you overcome the negative in order to get more positive support?
	16. You can manage stress	Provide an opportunity for parents to discuss and identify stressors in their life.	What causes you stress? When you are stressed, what do you do? When you are stressed, do you tend to eat or drink? How does stress effect you physically?
	17. Healthy breakfast	Improve the understanding of breakfast and how eating breakfast is beneficial to overall health. Identify strategies to eat a healthy breakfast.	Do you have time to eat breakfast? How often do you and your children eat breakfast? What happens if you don't eat breakfast? What do you eat or drink for breakfast? What are healthier options you could have for breakfast?
	18. Healthy routines	Brainstorm and discuss routines in everyday life. Explore ways to make routines a healthy part of life.	What routines do you have? Do you have any regular eating routines? What about any fitness routines? What about any snack routines? What about any mealtime routines?
	19. Food labels	Build skills in reading nutrition-fact labels. Make the connection between the information from the labels and making healthy food selections.	Do you read food labels? If so, what do you look at? Do you make purchases based on the nutrition information from the food labels? What are you most concerned with regarding the food labels?
	20. Jump start your activity plan	Provide an opportunity for parents to acknowledge and identify barriers to meeting their goals. Review the steps to problem solving.	Where are you with the progress of your activity goals? Have you met any of your activity goals? What has helped it you meet your activity goals? What has made it hard to meet your activity goals?
	21. Take charge of your	Recognize and identify negative thoughts. Assist parents in learning how to talk back to	Tell me the positive changes you have made. What are things you tell yourself to encourage your positive behavior?

	thoughts/Ways to avoid burnout	negative thoughts with positive thoughts. Encourage parents to get back up and on track after a slip.	What strategies have worked for you when you feel discouraged?
	22. Shopping	Identify strategies for healthy shopping. Build skills in creating lists to grocery shop for planned meals.	Who does the grocery shopping for the family? How often do you go to the grocery store? Do you have a strategy for grocery shopping? What pulls your attention when you are at the grocery store? What influences what you purchase at the grocery store?
	23. Stay motivated	Review the participant's progress and develop a plan for improvement. Discuss the importance of motivation and ways to stay motivated. Develop action plans for common barriers.	What have you been able to accomplish so far? What motivated you? How did you deal with any distractions that arose? What helped you stay on track with your goals? What will you continue to do to stay healthy?

M2 Appendix B. Data Safety and Monitoring Plan

Data and Safety Monitoring Plan
To assure that the safety of research participants is appropriately monitored and the validity and integrity of the data are ensured, we have defined operating procedures to regularly review data and outcomes. We have developed a Data and Safety Monitoring Plan that is commensurate with the scope of the research project. Therefore, considering minimal potential risks of this trial the plan operating procedures include the following:

Description of Monitoring Entities
The Principal Investigator (PI) is responsible for oversight of all aspects of the trial including safety and the inclusion of other reviewers does not relieve the investigator's responsibility. However, additional oversight will be provided by a Data and Safety Monitoring Board (DSMB).

Description of Plan for Interim Analysis and Reporting
Monitoring responsibilities include examination of safety, study protocol, data collection, and outcomes for the potential for adverse outcomes. We have appointed a DSMB. This board will evaluate the progress of the trial, including periodic assessments of participant risk versus benefit, safety, and other factors that can affect study outcome (to be described in detail in the DSMB Charter) annually and ad hoc as necessary. In accordance with the DSMB Charter and the determination made at the initial DSMB meeting, and at the discussion of the Chair, data will be provided to the DSMBat least annually. In the event of the identification of or potential for an adverse event, the PI will immediately notify the DSMB and the IRB.

Description of Plan for Assuring Data Accuracy, Data Security, and Protocol Compliance
The study has developed plans to assure data accuracy, data security, and protocol compliance. All study team members will receive training in data accuracy and security procedures. Study staff are required to notify the project manager and PI of suspected protocol deviations, and provide an explanation, within 24 hours of awareness (Monday-Friday). After review, the PI will categorize protocol deviations as either major (has the potential to negatively impact the rights, safety, or welfare of participants or others or the scientific validity of the study), or minor, and will track all deviations. For minor deviations, the staff member responsible for the deviation will be notified. If it is evident that the protocol is misunderstood, clarification will be provided. Repeated occurrence of a minor deviation may be classified as a major deviation. Major deviations will prompt the PI to requesting a written explanation from the responsible staff member. The project manager, as needed, and the PI will communicate with study personnel to confirm that a process is in place to ensure that further protocol deviations of similar kind do not recur. Review of all protocol violations will be a standard component of study team meetings. The study team will report major deviations to the IRB within 10 working days of the PI's awareness; if a major deviation results in SAE, the IRB will be notified within one working day of the PI's awareness.

Description of Mechanism for Reporting Adverse Events and Unanticipated Problems
Due to the minimal risk nature of the study, problems and adverse events are unlikely. However, the PI is responsible for reporting adverse events. Upon notification or observation of an adverse event, the PI will immediately notify the IRB and the program officer at NHLBI via telephone and email. Subsequent updating communications will take

place as necessary. Secondly, a detailed written description of the event and outcome will be sent to the DSMB, IRB, and NHLBI, including standard form reporting. Additionally, the DSMB and NIH will be informed of any actions taken by the IRB. The IRB and NHLBI will be notified of recommendations made by the DSMB. Annual progress reports to the DSMB, IRB, and NHLBI will summarize any adverse event and outcome.

M3 Appendix C.

HEALTH D&I (R01HL143360): Implications of COVID-19-Expanding for long-term data collection

Our team initially put in place temporary methods to allow for recruitment/enrollment and follow-up data collection to occur during COVID-19. However, these were designed to be temporary, and therefore did not incorporate collection of important secondary outcomes (i.e., blood pressure, waist circumference). Expanding on the plans to resume recruitment, enrollment, and follow-up data collection of our study in the context of COVID-19 requires additional changes to the study components noted below.

- Screening and Consent
- Participant Enrollment & Baseline Data Collection
- Post Visit Data Collection
- Intervention delivery and tracking

Noting that this study takes place across 40 sites, each of which operates differently, we anticipate this as a starting place for sites currently prepared to implement these protocols. We propose the following modifications:

Screening and Consent

Pre-COVID Procedures

Data collectors screened potential participants by phone or at site events to ascertain self-reported height and weight, to determine eligibility. If eligible based on self-report, the data collector consented the potential participant to an in-person baseline visit and scheduled this visit. It is at this in-person visit that the potential participant completed the consent process with the data collector and was given a hard copy of the consent document. There was no signed consent, but after the consent was reviewed, the data collector documented the consent process in RedCap.

COVID Procedures and Changes

The screening process will proceed as before with only the phone/video call option available (e.g. Zoom, FaceTime, Microsoft Teams, and Google Duo). If a potential participant screens as eligible, we will email or mail the potential participant the consent document. We will verify the participants email address by i) either encrypting the email with the consent attached or ii) by sending a confirmation email that does not include any PHI or study materials first and then sending the consent after confirmation, confirming they have received the consent document. Once the participant has received the consent documentation, we will complete the consent process over the phone. Due to the COVID-19 pandemic, data collectors will not be able to visit with potential participants in person, but will schedule a time for a second phone/video call conversation.

A scale, automated blood pressure cuff, and tape measure for assessing waist circumference will be sent to and stored local to the site. If the participant agrees to participate in the study, the study team will reach out to a PAT staff member (i.e., the participant's parent educator and/or the site leader) to coordinate data collection, check in on the availability of the equipment, and reinforce safety procedures as needed. Based on the preference from the site, this will proceed through one of 2 options:

1. Drop-off method: A PAT staff member or data collector (Wash U employee previously hired near the study site to assist with data collection) will drop-off and pick up data collection materials (i.e., scale, automated blood pressure cuff, and tape

measure) at her home. The PAT staff member or data collector will sanitize the materials using the wipes provided by the research team just before dropping them off and after picking them up. Ideally, these will be coordinated with planned trips to the home to drop of PAT-related materials (e.g., handouts, materials for activities during personal visits/group connections) or personal visits.

2. Site method: The data collection materials will be maintained at the site, and a private room will be available, where the mother can go to use the equipment. The site will follow COVID procedures per the protocols the site has established (these differ across sites based on conditions in the local community). If possible, this will be coordinated with a trip the mother was already planning to the PAT site.

In both cases, the PAT staff member will receive an incentive of $20 per data collection visit, which equates to $10 per dropping off or setting up the equipment before the visit and $10 for picking up or taking down the equipment after the visit, for their time and effort.

Participant Enrollment & Baseline Data Collection

Pre-COVID Procedures

After data collectors completed the consent process, they measured the participant's blood pressure and then gathered data to verify eligibility and enroll eligible participants into the study. This data consists of gathering their height and weight, to verify eligibility by ensuring the participant's measured (as opposed to self-reported)-BMI is in the eligible range. If the participant's eligibility is confirmed additional data collection includes: waist circumference and a survey that the participant completed in RedCap.

COVID Procedures and Changes

1. An approved scale, automated blood pressure cuff, and tape measure for assessing waist circumference will be mailed to each site. Once the PAT staff member or data collector has dropped off the scale, blood pressure cuff, and tape measure or the mother is situated in the private room at the PAT site we will either:
    a. Complete modified data collection via video call, in which we will i) see the participant stand on the scale; ii) use the automated blood pressure cuff; and iii) encircle her waist with the tape measure; these will be recorded entered live in REDCap.
    b. If the participant is not able to complete a video call, she will complete the data collection by phone, and will receive instructions by the research team on (i) how to take a weight on the scale, (ii) take a photo of weight with her personal device (e.g., phone, ipad), (iii) remove their location tags, and (iv) send a photo of their ID number and weight on the scale, the reading on the blood pressure cuff, and the location on the tape measure to the research team which does not include any identifying factors (e.g. face, location, or name).

    For all mothers, we will walk the participant through the process of setting up the scale, using the blood pressure cuff, and using the tape measure (e.g., locating the correct spot for assessing waist circumference). Further, we will utilize their self-reported height to calculate their BMI and ensure eligibility. Weight will be assessed first, as this is used to confirm eligibility. If the mother

is eligible, the remainder of the measures (blood pressure and waist circumference) will be completed.
2. The study team member will then conduct the RedCap Survey through the video call or over the phone.

Once the mother has completed data collection, the PAT staff member or data collector will collect the materials (i.e., scale, automated blood pressure cuff, and tape measure), sanitize them using the wipes provided by the research team, and stored local to the site. If the drop-off method is being used the pickup will ideally be coordinated with planned trips to the home to drop of PAT-related materials (e.g., handouts, materials for activities during personal visits/group connections) or personal visits.

Post Visit Data Collection

Pre-COVID Procedures

Given the ongoing nature of the COVID-19 impacts, enrolled participants will be reaching their first post (12-month) and possibly second (24-month) data collection visit. Our current data collection procedures are similar to participant enrollment procedures. The data that is gathered in the post data collection visits include: weight, blood pressure, waist circumference and a survey in RedCap.

COVID Procedures and Changes

As Data Collectors are no longer able to travel to gather certain data points from the participant, the following changes will be needed to continue the post data collection process.

1. Using the same data collection materials as enrollment/baseline and the same procedure (i.e., Drop-off/ pick up method or Site method):
    a. Complete modified data collection via the same procedures noted above for baseline (with the exception of self-reported height)
2. We will then conduct the RedCap Survey over the phone or video call.

For data collection at all time points, we will increase the amount of the participant incentive from $20 to $30, due to the increased time and effort on the part of the participant.

We recognize the dynamic nature of the pandemic situation. If a PAT staff member or data collector is not able to drop equipment off at the participant's house or the mother is not able to travel to the PAT site, we will revert to the procedures we used in the initial months of the pandemic (beginning in mid-March), which involved mailing a scale with instructions to the participant's home and scheduling a time for follow-up.

Intervention delivery

Consistent with the D&I focus of the study, we will follow each site's practice regarding whether and how visits continue (e.g., virtual, phone, in person). Recognizing the dynamic nature of the situation, we will coordinate with PAT National Center regarding data they are collecting at the site level in terms of what types of visits are being offered as well as what site leaders and parent educators indicate. Parent educators also still have the option to complete visit records for visits conducted virtually with mom's

enrolled in the study. The visit record form now has an item to indicate how the visit was conducted (i.e., in person vs virtual (phone/video conference).

Additional challenges

As we resume data collection at additional sites, and as sites who have not yet begun data collection start this process, we anticipate we may need to add additional options. We will communicate with sites about the process which will work best for them and if needed, request modifications accordingly.

References

1. Dutton GR, Kim Y, Jacobs DR, Jr., et al. 25-year weight gain in a racially balanced sample of U.S. adults: The CARDIA study. *Obesity (Silver Spring).* 2016;24(9):1962-1968.
2. Lewis CE, Jacobs DR, Jr., McCreath H, et al. Weight gain continues in the 1990s: 10-year trends in weight and overweight from the CARDIA study. Coronary Artery Risk Development in Young Adults. *Am J Epidemiol.* 2000;151(12):1172-1181.
3. Dietz WH. Obesity and Excessive Weight Gain in Young Adults: New Targets for Prevention. *JAMA.* 2017;318(3):241-242.
4. Harrison CL, Skouteris H, Boyle J, Teede HJ. Preventing obesity across the preconception, pregnancy and postpartum cycle: Implementing research into practice. *Midwifery.* 2017;52:64-70.
5. Walker LO, Sterling BS, Kim M, Arheart KL, Timmerman GM. Trajectory of weight changes in the first 6 weeks postpartum. *J Obstet Gynecol Neonatal Nurs.* 2006;35(4):472-481.
6. Williamson D, Madans J, Pamuk E, Flegal K, Kendrick J, Serdula M. A prospective study of childbearing and 10-year weight gain in US white women 25 to 45 years of age. *Int J Obes.* 1994;18:561-569.
7. National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey. *NCHS Fact Sheet-Januar y 2016* 2016; https://www.cdc.gov/nchs/data/factsheets/factsheet_nhanes.pdf. Accessed August 8, 2017.
8. Flegal KM, Kruszon-Moran D, Carroll MD, Fryar CD, Ogden CL. Trends in Obesity Among Adults in the United States, 2005 to 2014. *JAMA.* 2016;315(21):2284-2291.
9. Zheng Y, Manson JE, Yuan C, et al. Associations of Weight Gain From Early to Middle Adulthood With Major Health Outcomes Later in Life. *JAMA.* 2017;318(3):255-269.
10. Williamson DF, Kahn HS, Remington PL, Anda RF. The 10-year incidence of overweight and major weight gain in US adults. *Arch Intern Med.* 1990;150(3):665-672.
11. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002;346(6):393-403.
12. Diabetes Prevention Program Research Group. Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications over 15-year follow-up: the Diabetes Prevention Program Outcomes Study. *Lancet Diabetes Endocrinol.* 2015;3(11):866-875.

13. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *Circulation.* 2014;129(25 Suppl 2):S102-138.
14. Magkos F, Fraterrigo G, Yoshino J, et al. Effects of Moderate and Subsequent Progressive Weight Loss on Metabolic Function and Adipose Tissue Biology in Humans with Obesity. *Cell metabolism.* 2016;23(4):591-601.
15. Wadden TA, Anderson DA, Foster GD. Two-year changes in lipids and lipoproteins associated with the maintenance of a 5% to 10% reduction in initial weight: some findings and some questions. *Obes Res.* 1999;7(2):170-178.
16. Stefanick ML, Mackey S, Sheehan M, Ellsworth N, Haskell WL, Wood PD. Effects of diet and exercise in men and postmenopausal women with low levels of HDL cholesterol and high levels of LDL cholesterol. *N Engl J Med.* 1998;339(1):12-20.
17. Dattilo AM, Kris-Etherton PM. Effects of weight reduction on blood lipids and lipoproteins: a meta-analysis. *Am J Clin Nutr.* 1992;56(2):320-328.
18. The Trials of Hypertension Prevention Collaborative Research Group. Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure. The Trials of Hypertension Prevention, phase II. . *Arch Intern Med.* 1997;157(6):657-667.
19. Aziz Z, Absetz P, Oldroyd J, Pronk NP, Oldenburg B. A systematic review of real-world diabetes prevention programs: learnings from the last 15 years. *Implementation Science.* 2015;10(1):172.
20. Langeveld M, DeVries JH. The long-term effect of energy restricted diets for treating obesity. *Obesity.* 2015;23(8):1529-1538.
21. Hutfless S, Gudzune KA, Maruthur N, et al. Strategies to prevent weight gain in adults: a systematic review. *Am J Prev Med.* 2013;45(6):e41-51.
22. Anastasiou CA, Karfopoulou E, Yannakoulia M. Weight regaining: From statistics and behaviors to physiology and metabolism. *Metabolism.* 2015;64(11):1395-1407.
23. Webb VL, Wadden TA. Intensive Lifestyle Intervention for Obesity: Principles, Practices, and Results. *Gastroenterology.* 2017;152(7):1752-1764.
24. Weiss EC, Galuska DA, Kettel Khan L, Gillespie C, Serdula MK. Weight Regain in U.S. Adults Who Experienced Substantial Weight Loss, 1999–2002. *Am J Prev Med.* 2007;33(1):34-40.
25. Diabetes Prevention Program Research G, Knowler WC, Fowler SE, et al. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. *Lancet.* 2009;374(9702):1677-1686.
26. Price DW, Ma Y, Rubin RR, et al. Depression as a predictor of weight regain among successful weight losers in the diabetes prevention program. *Diabetes Care.* 2013;36(2):216-221.
27. Dutton GR, Gowey MA, Tan F, et al. Comparison of an alternative schedule of extended care contacts to a self-directed control: a randomized trial of weight loss maintenance. *International Journal of Behavioral Nutrition and Physical Activity.* 2017;14(1):107.
28. Beavers KM, Case LD, Blackwell CS, Katula JA, Goff DC, Vitolins MZ. Effects of weight regain following intentional weight loss on glucoregulatory function in overweight and obese adults with pre-diabetes. *Obesity Research & Clinical Practice.* 2015;9(3):266-273.

29. Johnson M, Jones R, Freeman C, et al. Can diabetes prevention programmes be translated effectively into real-world settings and still deliver improved outcomes? A synthesis of evidence. *Diabet Med.* 2013;30(1):3-15.
30. Ackermann RT, Marrero DG. Adapting the Diabetes Prevention Program Lifestyle Intervention for Delivery in the Community: The YMCA Model. *The Diabetes Educator.* 2007;33(1):69-78.
31. Neamah HH, Sebert Kuhlmann AK, Tabak RG. Effectiveness of Program Modification Strategies of the Diabetes Prevention Program: A Systematic Review. *Diabetes Educ.* 2016;42(2):153-165.
32. Tabak RG, Sinclair KA, Baumann AA, et al. A review of diabetes prevention program translations: use of cultural adaptation and implementation research. *Transl Behav Med.* 2015;5(4):401-414.
33. Whittemore R. A systematic review of the translational research on the Diabetes Prevention Program. *Transl Behav Med.* 2011;1(3):480-491.
34. Ritchie ND, Sauder KA, Fabbri S. Reach and Effectiveness of the National Diabetes Prevention Program for Young Women. *Am J Prev Med.* 2017;(in press).
35. Ali MK, Echouffo-Tcheugui J, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the diabetes prevention program? *Health Aff (Millwood).* 2012;31(1):67-75.
36. Jackson L. Translating the Diabetes Prevention Program into practice: a review of community interventions. *Diabetes Educ.* 2009;35(2):309-320.
37. Committee on Progress in Preventing Childhood Obesity. *Progress in Preventing Childhood Obesity. How Do We Measure Up?* Washington, DC: Institute of Medicine of The National Academies; 2006.
38. Lenfant C. Shattuck lecture--clinical research to clinical practice--lost in translation? *N Engl J Med.* 2003;349(9):868-874.
39. Wing RR, Hamman RF, Bray GA, et al. Achieving weight and activity goals among diabetes prevention program lifestyle participants. *Obes Res.* 2004;12(9):1426-1434.
40. Haire-Joshu D, Schwarz C, Lapka C, Schechtman K, Brownson R, Tabak R. A Weight Change Intervention Embedded in a National Home Visiting Program: A Randomized Trial. *American Journal of Preventive Medicine.* Under Review.
41. Parents as Teachers National Center. PAT Quality Assurance Guidelines. 2016; http://www.parentsasteachers.org/images/stories/QA_guidelines_May_2016.pdf. Accessed September 26, 2016.
42. Schellenberg ES, Dryden DM, Vandermeer B, Ha C, Korownyk C. Lifestyle interventions for patients with and at risk for type 2 diabetes: a systematic review and meta-analysis. *Ann Intern Med.* 2013;159(8):543-551.
43. Huxley R, Mendis S, Zheleznyakov E, Reddy S, Chan J. Body mass index, waist circumference and waist:hip ratio as predictors of cardiovascular risk--a review of the literature. *Eur J Clin Nutr.* 2010;64(1):16-22.
44. Samdal GB, Eide GE, Barth T, Williams G, Meland E. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses. *International Journal of Behavioral Nutrition and Physical Activity.* 2017;14(1):42.
45. Moyer VA, Force USPST. Screening for and management of obesity in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2012;157(5):373-378.
46. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and

implementation research to enhance public health impact. *Med Care.* 2012;50(3):217-226.
47. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci.* 2015;10:21.
48. Proctor EK, Landsverk J, Aarons G, Chambers D, Glisson C, Mittman B. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. *Adm Policy Ment Health.* 2009;36(1):24-34.
49. Baumann AA, Cabassa LJ, Wiltsey Stirman S. Adaptation in Dissemination and Implementation Science. In: Brownson R, Colditz G, Proctor E, eds. *Dissemination and Implementation Research in Health: Translating Science to Practice*. 2nd Edition ed. New York: Oxford University Press; 2018.
50. Glasgow RE, Klesges LM, Dzewaltowski DA, Estabrooks PA, Vogt TM. Evaluating the impact of health promotion programs: using the RE-AIM framework to form summary measures for decision making involving complex issues. *Health Educ Res.* 2006;21(5):688-694.
51. CFIR Research Team. Consolidated Framework for Implementation Research (CFIR). http://cfirguide.org/. Accessed June 27, 2017.
52. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci.* 2009;4:50.
53. Haire-Joshu D, Schwarz CD, Steger-May K, et al. A Randomized Trial of Weight Change in a National Home Visiting Program. *Am J Prev Med.* 2018;54(3):341-351.
54. Murray DM, Varnell SP, Blitstein JL. Design and analysis of group-randomized trials: a review of recent methodological developments. *Am J Public Health.* 2004;94(3):423-432.
55. Murray DM. *Design and Analysis of Group-Randomized Trials.* New York, NY: Oxford University Press; 1998.
56. Varnell SP, Murray DM, Janega JB, Blitstein JL. Design and analysis of group-randomized trials: a review of recent practices. *Am J Public Health.* 2004;94(3):393-399.
57. Ford I, Norrie J. Pragmatic Trials. *N Engl J Med.* 2016;375(5):454-463.
58. Pocock SJ, Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. *Biometrics.* 1975;31(1):103-115.
59. Stirman SW, Miller CJ, Toder K, Calloway A. Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implement Sci.* 2013;8:65.
60. Parents as Teachers National Center. *Foundational curriculum.* St. Louis, MO: Author; (2015).
61. Glanz K, Rimer BK, Lewis FM. *Health Behavior and Health Education: Theory, Research, and Practce.* 3rd ed. San Francisco, CA: Jossey-Bass; 2002.
62. Sallis J, Owen N. Ecological models of health behavior. In: Glanz K, Lewis FM, Rimer BK, eds. *Health behavior and health education. Theory, research, and practice*. 2nd ed. San Francisco, CA: Jossey-Bass; 1997:403-424.
63. Haskell WL, Lee IM, Pate RR, et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. *Med Sci Sports Exerc.* 2007;39(8):1423-1434.

64. Haire-Joshu D, Elliott MB, Caito NM, et al. High 5 for Kids: the impact of a home visiting program on fruit and vegetable intake of parents and their preschool children. *Prev Med.* 2008;47(1):77-82.
65. Haire-Joshu D, Nanney MS, Elliott M, et al. The Use of Mentoring Programs to Improve Energy Balance Behaviors in High-risk Children. *Obesity.* 2010;18(S1):S75-S83.
66. Haire-Joshu DL, Schwarz CD, Peskoe SB, Budd EL, Brownson RC, Joshu CE. A group randomized controlled trial integrating obesity prevention and control for postpartum adolescents in a home visiting program. *Int J Behav Nutr Phys Act.* 2015;12(1):88.
67. Kegler MC, Alcantara I, Haardorfer R, Gazmararian JA, Ballard D, Sabbs D. The influence of home food environments on eating behaviors of overweight and obese women. *J Nutr Educ Behav.* 2014;46(3):188-196.
68. Wiltsey Stirman S, Calloway A, Toder K, et al. Community mental health provider modifications to cognitive therapy: implications for sustainability. *Psychiatr Serv.* 2013;64(10):1056-1059.
69. Stuckey HL. The second step in data analysis: Coding qualitative research data. *J Soc Health Diabetes.* 2015;3:7-10.
70. Strauss A. *Qualitative Analysis for Social Scientists.* Cambridge, UK: Cambridge University Press; 1987.
71. Strauss A, Corbin J. *Basics of Qualitative Research: Second Edition: Techniques and Procedures for Developing Grounded Theory.* 2nd ed. Thousand Oaks, CA: Sage Publications; 1998.
72. Patton MQ. *Qualitative Evaluation and Research Methods.* 3rd ed. Thousand Oaks, CA: Sage; 2002.
73. QSR International. NVivo10. http://www.qsrinternational.com/product. Accessed March 19, 2017.