Effectiveness of Health Coaching to Reduce Cardiometabolic Risk in Early Home Visiting Services

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Version 2	Date: 6/6/2022	Description: Slight clarification was added to section 8 to describe the role of the home visitor in recruitment. This change reflects the recruitment changes made in section 13 of the eIRB.

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1. SUMMARY

Black and Latina women have the highest prevalence of obesity[1]. Women entering pregnancy with obesity have an excess risk of gestational diabetes, hypertensive disorders, and acute cardiovascular event during labor and delivery, compared to normal weight women[2,3]. Because pregnant women are motivated to have a healthy baby, pregnancy provides the ideal "teachable moment" to not only reduce adverse pregnancy outcomes, but ultimately prevent long-term cardiometabolic disease (CMD) in women and their infants[4,5]. Lifestyle interventions addressing obesity in pregnancy have the potential to break the cycle of obesity and CMD for Black and Latina women[6]. However, despite evidence of effectiveness, few lifestyle interventions have been tested among Black or Latina pregnant women or implemented in community-based settings, where many high risk pregnant and postpartum women access safety-net services. To address this gap, we will leverage our team's experience designing and testing an evidence-based pregnancy/postpartum health coaching intervention, Healthy for Two (H42), that is remotely delivered (phone coaching using motivational interviewing + web-based platform + mobile phone behavioral tracking). Along with our Maryland home visiting partners, we will adapt and implement H42 into the home visiting setting, i.e., H42-HV and tailor the intervention for Latina and Spanish speaking women and their infants. Early home visiting is an evidence-based public health service strategy found in all 50 states that targets services to high-risk communities to address adverse social determinants of health. Home visitors provide health education, promote positive parenting and early learning, and link families with needed community resources[7]. While home visiting programs don't universally prioritize CMD risk in their services, they are an ideal service-strategy for integration of a healthy lifestyle intervention.

We will use a hybrid type 1 effectiveness-implementation randomized control trial to compare the effectiveness of H42-HV integrated into home visiting compared with usual home visiting services in reducing postpartum weight retention (difference between pre-pregnancy weight and weight at 6 months postpartum) among 400 pregnant and postpartum women. We will also evaluate the implementation of the intervention to enable and sustain integration into home visiting. Ultimately, we aim to prevent CMD and its intergenerational effects by promoting healthy lifestyle and postpartum weight loss and addressing disparities in CMD among Black and Latina pregnant/postpartum women at highest risk and support for healthy infant growth from the start. Our approach allows us to not only establish the effectiveness of H42-HV but also understand the factors that enable intervention implementation to inform sustainability, further the pathway from evidence translation into practice, and facilitate greater subsequent public health impact [8].

2. AIMS AND OUTCOMES:

We will conduct a type 1 hybrid effectiveness-implementation trial to evaluate Healthy for Two – Home Visiting (H42-HV).

Aim. Compare the effectiveness of H42-HV integrated into home visiting compared with usual home visiting services in reducing **postpartum weight retention** (PPWR; difference between pre-pregnancy weight and weight at 6 months postpartum) among 400 pregnant and postpartum women.

Primary outcome: postpartum weight retention at 6 months after delivery (difference between pre-pregnancy weight and weight at 6 months postpartum)

> **Main hypothesis**: H42-HV integrated into Maryland home visiting programs will reduce PPWR compared to usual home visiting comparison group.

Secondary maternal outcomes: gestational weight gain, maternal health behaviors (diet, physical activity, smoking, breastfeeding); maternal wellness (depression, sleep, social support, and stress); maternal health care utilization (postpartum OBGYN visit, PCP visit by 6 months)

Secondary infant outcomes: infant growth; newborn healthcare utilization (well infant visit receipt).

In addition to establishing effectiveness, we have an implementation aim that seeks to understand the factors that enable intervention implementation [9]; however, those outcomes and methods will be covered by a different IRB protocol.

3. BACKGROUND AND RATIONALE FOR THE STUDY

This trial was funded as one of 3 studies in the Mid-Atlantic Center for Cardiometabolic Health Equity (MACCHE) (P50). We are building on strong, existing partnerships with Maryland early home visiting programs serving low-income Black/African American and Latino communities. We will leverage our team's experience designing and testing "Healthy for Two/Healthy for You" (H42), an evidence-based health coaching intervention (phone coaching + web-based platform + mobile phone behavioral tracking), designed to prevent cardiometabolic disease (CMD) in pregnant and postpartum women [8,10,11,12] (IRB IRB00255969). Along with our home visiting partners, we will adapt and implement H42 into the home visiting setting, i.e., H42-HV. Ultimately, we aim to prevent CMD and its intergenerational effects by promoting healthy lifestyle and postpartum weight loss among low-income Black and Latina pregnant/postpartum women at highest risk for CMD and their infants.

Racial and ethnic inequities exist for obesity and maternal health outcomes. Despite two decades of public health efforts to combat obesity, rates continue to rise[13,14]. Almost 40% of adults in the United States (US) are obese, with increasing prevalence among women[13] and significant disparities by race[15]. In 2017-18, the prevalence of obesity was 40% for non-Hispanic White women, 44% for Hispanic (referred to hereafter as Latina) women, and 57% for non-Hispanic Black/African American (referred to hereafter as Black) women[1]. In Maryland, only 44% of women enter pregnancy at a normal weight[16]. In fact, Black and Latina

women are more likely to enter pregnancy with an elevated body mass index (BMI), have excessive gestational weight gain (GWG), and thus greater risk for future obesity from postpartum weight retention (PPWR) after delivery, compared to White women[3,8,17,18]. Maternal obesity has been implicated in worsening disparities in maternal mortality in the US and Maryland, which disproportionately impacts Black women [19,20,21,22,23,24].

Obesity prevention efforts need to re-focus on women of reproductive age with greatest risk of disparities. Significant weight gain of ≥20kg through adulthood is associated with a 2-fold increased risk of hypertension and cardiovascular disease (CVD) and 30% greater overall mortality[25]. 23% of women (vs. 13% of men) gain ≥20kg from age 18 to 55 years and weight gain in young adulthood is highest for Black women who gain >1kg/year[26,27], often due to PPWR. To address the obesity epidemic, there is an urgent need for obesity prevention efforts to target high risk women of reproductive age, especially during pregnancy and the postpartum period[25, 27,28]. Because pregnant women are motivated to have a healthy baby, pregnancy provides the ideal "teachable moment" to not only reduce adverse pregnancy outcomes (e.g., hypertensive disorders of pregnancy and gestational diabetes), but ultimately prevent CMD in women and their infants[29,5] since rapid infant weight gain disproportionately affects low-income and ethnic minority groups and may explain disparities in childhood obesity[30-34].

The postpartum period provides ideal opportunity to improve care transitions, sustain healthy behaviors to reduce CMD. In addition to pregnancy serving as a window to women's future CV health, the postpartum period represents a vulnerable time for many women, particularly for socially disadvantaged women and those with a history of pregnancy complications[35,36]. In fact, the American College of Obstetricians and Gynecologists suggested a re-design of postpartum care to reduce severe maternal morbidity and mortality, including counseling around postpartum weight loss, blood pressure monitoring and smoothing the transition into primary care[37]. Our own research has shown gaps in postpartum care— women with recent preeclampsia and GDM have low primary care follow-up rates in the one year after delivery, regardless of insurance type, and tend to rely on the emergency room for care[38,39]. Notably, few programs exist that target the postpartum time period to promote women's self-care, diet, and exercise to reduce PPWR and ultimately decrease obesity and CMD risk[37]. To reduce long-term CMD risk in women, it is crucial to extend behavioral interventions beyond pregnancy and into the postpartum period for women at highest risk for future CMD.

Evidence supports behavioral programs in pregnancy to improve maternal health outcomes, but few studies included Latina women. Strong and increasing evidence, now demonstrated in multiple trials in diverse populations and a growing number of meta-analyses, supports behavioral interventions to limit GWG and PPWR and improve health behaviors[6, 40,41,42,43,44,45,46].However, Latinas were underrepresented in behavioral weight loss intervention studies[6]. A recent systematic review found that across 94 behavioral weight loss intervention trials, less than 10% of participants were Latino [47]. While social support has been identified as a key facilitator of healthy behaviors among Latinas, they have been found to receive limited social support for physical activity[48,49,50]. Therefore, successful behavioral interventions need to address the culturally relevant social and environmental factors that support and impede healthy behaviors, specific to each population's needs.

Early home visiting—an ideal service strategy for the delivery of a CMD behavioral health promotion intervention because attention to social determinants of health. Evidence-based early home visiting is a public health preventive strategy for pregnant women and families with children birth to 5 years. Services target high-risk communities to address adverse social determinants of health through education and support to promote health equity for families facing adversity, such as poverty. Early home visiting has been shown to increase school readiness, improve maternal and child health, promote positive parenting, reduce child maltreatment, increase referrals and linkages to community resources, and improve family economic self-sufficiency[7]. Because exposure to adverse neighborhood environmental factors contribute to racial disparities in obesity and CMD, including lack of healthy food availability, low walkability, limited greenspace, and high crime[51,52,53] , safety-net public health programs like early home visiting are uniquely positioned to address these social determinants.

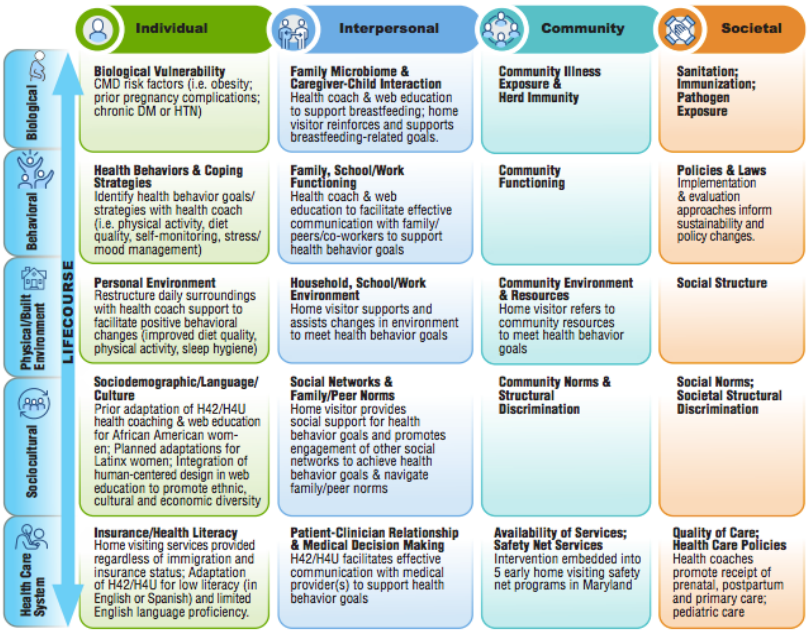
Improvement of maternal and infant CMD is not (yet) a focus in early home visiting. While home visiting studies have demonstrated some improvements in maternal health (i.e., more frequent prenatal care, early detection/treatment of depression) and child health (i.e., vaccine rates), studies of home visiting services have not demonstrated or even examined maternal or infant CMD risk. Furthermore, from our prior research only 8 of the 19 national evidence-based home visiting models even enroll families prenatally. Of those 8, only 6 specify a goal of improving birth outcomes[54]. Of the 6 models that prioritize birth outcomes, maternal high blood pressure, diabetes, and tobacco use are not universally targeted despite their central role in preventing adverse birth and pregnancy outcomes[54].

Health Disparities Impact. To address gaps in the availability of patient-centered behavioral health programs in pregnancy and postpartum, we will test the effectiveness and implementation of a tailored and targeted evidence-based health coaching intervention for Black and Latina pregnant/postpartum women, embedded into early home visiting services. Home visiting programs are uniquely positioned to help overcome adverse social and environmental conditions that may act as a barrier to health lifestyles as they emphasize social support, culturally informed care, coordination with community resources, strengths-based assessments, and collaboration to support self-identified goals[55]. This intervention has the potential for wide-scale translation into this safety-net service strategy to address disparities in CMD among women and their infants.

4. CONCEPTUAL FRAMEWORKS

4.1. NIMHD Research Framework. We adapted the NIMHD research framework for the H42-HV intervention (**Figure 1** (56)). This framework reflects the multi-factorial influences on CMD and disparities, including the social determinants of health. The H42-HV intervention delivered by the health coach + home visitor is focused on promoting individual-level behavior change. Embedding the intervention into early home visiting and creating a health coach + home visitor team, expands the intervention beyond the individual level and engages the multi-factorial influences by training the home visitor to support health behavior goals setting by addressing interpersonal-, community-, level determinants of health within the local context. The H42 -HV intervention addresses the **individual-level** by targeting women with CMD risk factors, regardless of insurance status or literacy level, identifying individual health behavioral goals, and using strategies that have been culturally adapted for Black and Latina women. At the **interpersonal-level**, health coaches support communication with family/peers/co-workers and health care providers to support behavior goals; home visitors provide social support and connect participants with other social support networks that promote healthy lifestyles. At the **community-level**, home visitors will assist with creative strategies for overcoming barriers presented by the physical environment and provide referrals to additional community resources. And at the societal-level, home visitors promote utilization of postpartum and primary care visits for women and infants and the study is designed to promote sustainability and home visiting policy change.

Figure 1. NIMHD Research Framework Adaptation for H42/H4U-HV



5. STUDY DESIGN AND RANDOMIZED GROUPS

5.1. Study design. The design of the study is a randomized, two parallel-arm clinical trial. We will be applying principles of a hybrid type 1 effectiveness-implementation randomized control trial57.

5.2. Randomized groups

5.2.2 Intervention Group: Healthy for Two -Home Visiting (H42-HV)

Those assigned to the intervention group will receive the 8 to 14 month H42 health coaching intervention in addition to usual home visiting and usual prenatal and postpartum care clinical services. Intervention duration will depend on the participant's gestational age at the of enrollment. Participants can be enrolled as early in pregnancy as 12 weeks gestation and as late as 33 weeks gestation. All participants would be enrolled for 6 months postpartum.

Therefore, the minimum time in the intervention would be 8 months and maximum would be 14 months.

5.2.3 "Usual Home Visiting Plus" Comparison Group (mHIP-HV)

Those assigned to the "usual home visiting plus" comparison group, called maintain health in pregnancy (mHIP-HV), will receive the typical, evidence-based experience in their home visiting program in addition to their usual prenatal and postpartum care clinical services. In addition, we will provide a brief (less than 5 minutes) maternal warning signs educational video that is available in English or Spanish. The video was developed for a home visiting client audience and is publicly available, https://mdmom.org/warningsigns.

6. STUDY POPULATION AND ELIGIBILITY

As a hybrid effectiveness-implementation trial we will apply to the broadest population of pregnant women possible. Participants will meet all of the following eligibility criteria: Age≥18; Singleton pregnancy ≤ 33 weeks gestation; self-reported pre-pregnancy weight and height with calculated BMI ≥ 25.0 kg/m^2; English or Spanish speaking; Enrolled in one of the participating home visiting sites; without active substance use disorder (except marijuana).

Other key eligibility criteria are listed in the **Table 1** below.

Table 1. Eligibility criteria
Inclusion criteria
• Age ≥18 years
• Pregnant, ≤33 weeks gestation
• Singleton pregnancy
• Pre pregnancy BMI≥25.0 kg/m^2 (calculated based on self-reported pre pregnancy height and weight)
• Able to provide informed consent
• English or Spanish speaking
• Enrolled in participating home visiting program
• Completion of screening and baseline data collection
• Willing to participate in the intervention and data collection procedure (e.g., home weights)
Exclusion criteria
• Age <18 years
• Type 1 diabetes or taking insulin prior to delivery
• > 33 weeks gestation
• Pregnant with multiple fetuses
• Unable to walk 1 block without pain or shortness of breath
• Not cleared by the study's clinicians or home visiting program staff
• Planning to relocate from area during next 1 year
• Active substance abuse disorder (except marijuana)
• Psychiatric or substance use related hospitalization in past 1 year
• Active eating disorder

7. STUDY SETTING

We will be recruiting and enrolling pregnant patients from a variety of Maryland early home visiting programs. Many of these programs are housed in local health departments (e.g., Washington County Healthy Families America, Prince George's Healthy Families America, Garrett County Healthy Families America, Dorchester County Healthy Families America) or community-based organizations (e.g., DRUM Healthy Families America, Family Tree Healthy Families America, Baltimore Healthy Start, Lourie Center Head Start, Mary's Center Healthy Families America).

Role of the Home visiting programs:

The home visiting programs will not be engaged in human subjects research, as it is defined under the Department of Health and Human Services – Office for Human Research Protections. We have designed this project with these principles:

- The home visiting programs will not perform informed consent for the study. Only study staff will perform informed consent.
- The home visiting program staff will not deliver the intervention to or collect data from study participants. They will receive general training about the intervention and how to support clients who are receiving the H42-HV intervention but will not deliver the intervention to or collect data from their clients who are study participants.
- The home visiting programs will share study recruitment information and materials for self-referral; they will also be able to refer interested clients to the study with the client's permission.

8. RECRUITMENT

8.1. Overview of the Recruitment, Screening and Enrollment Process (Table 2)

Our recruitment procedures are outlined in **Table 2**. We will follow a similar protocol for recruitment as in our recently completed pilot study and ongoing pragmatic trial study (IRB00307430).

Table 2. Recruitment, Screening and Enrollment, embedded into Home Visiting Programs

Step 1	At time of enrollment into home visiting program
Home visiting programs	• Home visiting staff will provide potentially eligible clients with study recruitment materials, which will be in one or more of the following formats: conversation, e-mail, text messaging, shared video or paper. • If potentially interested, home visiting staff: 1) after obtaining client permission, may directly refer client to Study Team via secure communication system, similar to the process for referring clients to other services; 2) may assist clients to complete the online "interest form"; 3) advise clients to complete the online "interest form" on their own time. • To be eligible for the study, women must be enrolled in a participating home visiting study and therefore the home visiting staff will already have their PHI for programmatic purposes. The home visiting program staff will not be involved in screening, consent, or enrollment and will not know who has indicated interest in participating in the study unless the woman asks them to make the referral on their behalf.

Step 2	**Assess continued interest by research staff – by phone, email or text**
Phone screening + consent	• Research staff reaches out to home visiting client to assess interest and screen for eligibility • If medical or psychiatric concerns based on self-reported responses in screening, review by the Study Co-investigators • Phone-assisted electronic consent completed, including prenatal and infant medical record and claims data release consent
Step 3	**Completion of baseline surveys (online or phone assisted) + Medical Record Review**
Baseline surveys + medical record review	• Baseline online (or phone assisted) surveys completed • Study staff confirms pre-pregnancy weight using medical records received from prenatal care clinic • Participant receives, sets up and measures home body weight on the home scale provided by the study
Step 4	**Randomization by research staff – by video conference, phone or in person**
Enrollment/ Randomization assignment to H42-HV or mHIP-HV	• Once the participant has completed the baseline survey and has registered one weight on the home study scale, research staff will schedule a mutually convenient time for the randomization visit. The randomization procedure will follow similar procedures to those established for our ongoing pragmatic trial (IRB00307430). • Randomization must be complete by 34-weeks gestation.

8.2. Description of the recruitment and screening steps

- **Step 1.** The goal with recruitment for this hybrid effectiveness-implementation trial is to emulate the referral process from home visiting to other services and programs, such as a referral to WIC services or a food pantry. We have discussed the recruitment with all home visiting partners and received feedback about alignment of the screening and recruitment process with their intake processes.

  Home visiting staff will provide potentially eligible clients with study recruitment materials, which will be in one or more of the following formats: conversation, e-mail, text messaging, video or paper flyer. The recruitment materials will have information on completing an "online interest form" to share contact information. If potentially interested, home visiting staff: 1) after obtaining permission, could refer the client to Study Team, similar to the process they use for referring clients to other services; 2) assist clients with completing an online "interest form"; 3) advise clients to complete the online "interest form" on their own time.

- **Step 2**: Study staff will complete phone screening and online/phone-assisted consent via REDCap. Consent will also involve signing a medical record release form to obtain copies of their prenatal care records and providing "minimally necessary personal data" to link the participant with their medical claims (full name, date of birth and either social security number or Medicaid ID) for participants who are enrolled in Maryland Medicaid. Copies of consent forms will be e-mailed or postal mailed to participants.

- **Step 3:** Following consent, participants will complete baseline data collection involving an online or phone-assisted survey (see Table 3) and instructions for home weight measure using the study-provided scale that will be delivered to their home.

- **Step 4:** Randomization will indicate study enrollment and occur after participant meets all eligibility criteria, has completed the baseline survey and the study team has received one

valid weight from the participant's cellular enabled scale. Participants will be randomized using an online/phone-assisted protocol. As part of our ongoing trial, our study team has already designed and implemented a REDCap assisted online consent and randomization process that we will employ for this study as well.

9. DATA COLLECTION AND MEASUREMENTS

9.1. Overview of measures, instrument and data sources

Table 3 summarizes the measures (with references to the standard instruments) we will use and the timing of data collection aimed at minimizing participant burden. Data will be collected using 4 methods: online surveys, home scale, medical record review, and Medicaid claims data.

Table 3. Aim 2A Measures, instruments, data sources and frequency of data collection

Measures and Instruments	Data source(s)	Timing				
		BL	36-38wk	2 mo	4 mo	6 mo
Demographics, preferred language, acculturation, & medical history58,59	Online (+ phone assisted) surveys	x				
Discrimination experiences 60	Online (+ phone assisted) surveys	x				
Postpartum weight retention (PPWR)	Pre-pregnancy height & weight (prior to 15 wks) from medical records	x				
Gestational weight gain (GWG)	37-weeks & postpartum weights from home scale		x	x	x	x
Safety net services & home visiting care utilization and experiences	Online (+ phone assisted) surveys	x	X	x	x	x
Maternal health care utilization	Claims + Online (+ phone assisted) surveys		x	x	x	x
Health behaviors (diet61,62; physical activity63; alcohol, marijuana, tobacco use 58; breastfeeding64)	Online (+ phone assisted) surveys	x	x	x	x	x
Maternal wellness (depression65, stress66, sleep67, social supports68)	Online (+ phone assisted) surveys	x	x	x	x	x
Infant weight and length (birth weight and 2, 4, and 6 months weights)	Online (+ phone assisted) surveys & medical records			x	x	x
Infant health care utilization	Claims + Online (+ phone assisted) surveys			x	x	x

Abbreviations: BL=baseline; mo=months postpartum; wk=weeks gestation.

9.2. Medical record review

"Baseline pregnancy" weight will be defined as the earliest measured weight in prenatal care obtained from prenatal medical records. We will also abstract height, blood pressure and co-morbid conditions from medical records. Participants will consent to prenatal and infant medical record release during the consent process. Most of our participants will not be Johns Hopkins patients. For the few participants who are Johns Hopkins patients, following consent to review medical records, the study team will access medical records via the Epic for manual data extraction of height, weight, and comorbid conditions. We will not be submitting a CCDA request. For all non Johns Hopkins patients, we will be requesting their medical records directly from their prenatal care provider via secure fax or secure email.

9.2. Assessment of maternal weight using the Home Scale

Maternal weights (measured at 37-weeks, 2 months, 4 months, and 6 months postpartum) will be measured in light indoor clothes without shoes and recorded by a home **study scale** (BodyTrace or a similar product) and recorded and transmitted to the study team automatically using cellular connectivity (no WIFI or cellular plan required). The scale will be delivered to the participant's home upon enrollment. The cellular enabled scales provide valid weight measures and have been used by several large-scale weight interventions[69].

9.3. Online Questionnaires, administered using REDCap – in English and Spanish languages

We have designed questionnaires using standard instruments (Table 3). Questionnaires were selected to minimize participant burden and enable completion at home.

9.3.1 Demographics, family characteristics and acculturation

We will collect maternal, infant and family health and demographic characteristics using standard surveys from CDC Pregnancy Risk Assessment Monitoring Survey (PRAMS).[53,54]

9.3.2 Smoking, Marijuana, and Alcohol

We will assess smoking, marijuana, and alcohol use using the PRAMS. [53,54]

9.3.3 Utilization of care

We will assess utilization of care using questions from PRAMS. [53,54]

9.3.4 Dietary Intake

We will assess dietary intake using the NHANES 2009-10 Dietary Screener Questionnaire (DSQ) Eating Habits Questionnaire[61], fast food frequency using the Coronary Artery Risk Development in Young Adults (CARDIA) Study questionnaires and sugar sweetened beverage intake using the NHANES questions[61].

9.3.5 Physical Activity

We will assess physical activity using the International Physical Activity Questionnaire – Short Self-Administered Format[63].

9.3.6 Women's Wellness and Mood

We will assess women's wellness through measures assessing mental health, social support, perceived stress, and sleep quality. We will assess depression and anxiety using the Edinburgh Postpartum Depression scale[65], which we modified to remove the question on suicidality. We will assess perceived stress using the Perceived Stress Scale and Social Support will be measured using the Medical Outcomes Study Social Support Questionnaire[68]. Sleep quality will be measured using the Pittsburg Sleep Quality Index[67].

9.3.7 Breastfeeding Practices and Infant health

We will use several questions from the standard and core measures of the CDC Pregnancy Risk Assessment Monitoring Survey (PRAMS), including use of community and safety net programs, pregnancy intention, usual source of care and infant overall health[58]. We also use the PRAMS to breastfeeding intention during pregnancy. We will assess ongoing lactation

practices after delivery (2, 4 and 6 months) using standardized measures from the CDC-Infant Feeding Practices Survey 64.

9.3.8. Racial Discrimination

We will assess discrimination using the 6-item short form discrimination scale 70.

9.3.10. Home visiting service utilization; Safety net services and home visiting care utilization and experiences

We will ask participants about their utilization of safety net services (i.e., Supplemental Nutrition Program for Women, Infants, and Children, Supplemental Nutrition Program). We will ask about the frequency of and satisfaction with home visiting services.

9.3.11. Satisfaction Survey with the H42-HV Intervention Components

We will assess satisfaction with Health Coaching, Mobile Phone tracking, web-based platform by participants and providers at study completion using a survey tool our team has designed and tested.

9.4. Medicaid claims data. We will request and obtain a data extract of Maryland Medicaid data for all consented participants to assess maternal and infant healthcare utilization outcomes (i.e., attendance at prenatal care visits, postpartum OBGYN visit, primary care visits, infant visits, receipt of infant vaccines). We will have a data use agreement with the Maryland department of health.

10. QUALITY ASSURANCE AND QUALITY CONTROL

Quality Assurance pertains to activities that promote collection of high-quality data, and Quality Control refers to activities that detect emerging data issues with sufficient time to implement appropriate corrective actions. Our approach to Quality Assurance includes: 1) preparing manuals of operations; 2) implementing a master trainer model to train and certify other staff; 3) train and certify all data collectors and recertify data collectors at least annually; 4) maintain logs of certified staff and equipment.

Our approach to Quality Control includes: 1) monitoring counts of completed data collection items through automatic flags in database; 2) running routine reports for missing surveys and flagging unusual data values and data inconsistencies for possible correction measures; 3) reviewing types and distribution of data entry errors/issues and remedying any systematic concerns; and 4) adjusting data inconsistency by endpoint assessment committee to decide possible action and documenting decision made for any data correction prepare reports for staff, investigators and NIMHD and the Safety Officer on Quality Control (see Data Safety and Monitoring Plan).

11. RANDOMIZATION AND BLINDING/MASKING

400 participants will be randomized 1:1 to H42-HV or the mHIP-HV comparator arm. Randomization will be stratified by home visiting site, BMI (BMI ≥30 kg/m^2 vs. 25-30 kg/m^2), and gestational age at enrollment, and within each stratum using randomly varying block sizes of 2, 4, and 6. The study's Lead Biostatistician will generate the randomization schedule.

Blinding: Due to the nature of the lifestyle intervention, participants and home visitors and intervention team will not be blinded to randomization assignment. Data collectors will be blinded to assignment. Until the end of the trial all non-intervention team study co-investigators will also remain blinded, except the Lead Biostatistician.

12. INTERVENTION – HEALTHY FOR TWO-HOME VISITING (H42-HV)

12.1. Overview of the H42-HV Intervention components (Table 4)

The intervention draws upon the strengths of preeminent theories from other behavioral weight loss and CVD risk reduction trials [12,71,72], including social cognitive theory and behavioral self-management concepts [73,74], enhanced by the application of our health coaching framework called COACH. H42-HV employs behavioral strategies such as goal setting, self-monitoring, problem solving and identification of strengths for overcoming barriers utilizing a patient-centered approach. Health coaches will be trained in motivational interviewing, an evidence-based approach aimed at enhancing participants' intrinsic motivation to change their health behaviors, including diet and exercise, and sleep and stress/time management, and to allow for the personalized and adaptive nature of the intervention[75,76,77].

Table 4 describes the three components of the H42-HV intervention: 1) Health Coaching Calls; 2) Online Platform for Learning Activities and Goal Setting Functions; 3) Tracking of health behaviors (diet, exercise), and 4) Self-weighing (weekly). The overarching behavioral goals of the intervention are for participants to have lower postpartum weight retention at 6 months after delivery. Weight and behavioral goals will be promoted through the COACH Framework, a behavioral model guiding coaching calls, behavioral tracking targets and learning activities. Coaches will refer to home visitors for additional support and community resources, based on an established protocol.

Table 4. H42-HV Description and Approach	
COACH Framework to promote weight goals & CMD prevention	**C**ommitment to self, baby and program **O**mission of high salt/high sugar foods **A**ddition of vegetables + exercise **C**ommunication with coach, home visitor **H**onor yourself through wellness, self-care
Components of program	
Health coaching	Training in patient-centered motivational interviewing approach with supervision by Health Coach Managers (with individualized case management) Starts as late as 33-weeks gestation to 6 months postpartum Phone or video contacts (~20 mins) ~7 in pregnancy/~6 PP
Interactive online learning platform	Learning activities focus on nutrition education, behavior change strategies, wellness (e.g. sleep, mood), long-term CMD prevention; English and Spanish versions
Health behavior tracking	Tracking of diet and exercise (via mobile app or paper/pencil)
Weekly self-weighing	Weekly self-weighing at home on BodyTrace scale
Cardiometabolic risk reduction - Behavioral Goals	
Smoking	Smoking cessation; Avoid second-hand smoke exposure
Pregnancy weight	Within recommended total weight gain[78]
Postpartum	Weight: Lose 2% pre-pregnancy, based on pre-pregnancy BMI was ≥25.0 kg/m^2 [79] Care: Transition to primary care[37] Promote breastfeeding[80]
Physical activity	≥150 min/week walking (or other moderate exercise)
Diet	↓ fast/junk foods with salt, added sugar, ↑ fruit/vegetables, using DASH Diet and MyPlate principles[81]
Role of Home Visitors and Home Visiting Program	

Supportive role, community resource	Facilitate intervention adherence, including contacts and behavioral goals, i.e. may include healthy shopping, postpartum + primary care appointment and pediatric appointment attendance.

12.1.a. Telephone health coaching calls by trained health coaches. Calls start at enrollment, as early in pregnancy as possible (latest start will be 33-weeks gestation) through 6 months postpartum. Although coaching calls will occur by phone (~20 mins), when possible, some coach contact could occur at the time of home visits in person, or via video interface.

12.1.b. Online interactive Learning Activities. Our literacy adaptation ensured Learning Activities are at ≤5th grade reading level. All activities are being translated into Spanish and culturally adapted to create a parallel program. Online learning activities contain embedded images (people and settings) that reflect the diversity of our target population, examples of activities that are readily available in the community and maximize the use of white space, large text and simple graphics to enhance readability and accessibility of the educational content. We enhanced the platform to enable an interactive goal-setting functionality for participants to set health goals paced with their Learning Activities and calls. The online program is maintained and monitored by the study's health coach managers.

12.1.c. Health behavior tracking (diet and exercise). Participants will receive specific skill-building on how to track diet and exercise behaviors via mainstream mobile app or paper/pencil, using procedures from our current trial. Coaches will be able to discuss tracking data with participants. Mainstream tracking apps are available in both Spanish and English.

Table 5. Example checklist for home visitors to support intervention participants

Web-based educational learning activities
Completes Learning Activities
Health coaching communication
Establishes communication with Health Coach Completes coach contacts
Technology access
Access to device (tablet or phone) Able to log-in to mobile tracker Able to log-in to web-based program Has data plan enabling access to programs
Health behavior tracking (via mobile app or paper/pencil)
Self-weighs at least once per week
Tracked 1 or more food item in last 3 days
Individual Goals & Knowledge (change weekly)
Knows pregnancy weight gain goals
Knows exercise goals
Knows diet goals
Identifies barriers to healthy eating and exercise
Assess barriers to healthful eating goals
Assess barriers to exercise goals

12.1.d Weekly self-weighing. Participants will be asked to weigh themselves weekly at home using their study scale.

12.1.e. Support from home visitors. In collaboration with our home visiting program partners we designed the role of the home visitors to be aligned with the procedures they already use in their program and visits. Because home visitors routinely complete "checklists" for a variety of health topics during home visits, we designed a H42-HV checklist for the home visitors (**Table 5**).

Home visitors will receive training on the program and use of a checklist that involves tasks within their scope of work focused on reaching intervention and behavioral goals and aimed at identifying and addressing social determinants of health. A Home Visiting Coach Manager will ensure appropriate supervision of health coaches, reporting and task completion. Coaches will reach out to home visitors when participants miss coach calls, when participants need help with community

resources and referrals (e.g., food assistance applications, identifying places to purchase healthy food, and finding appropriate exercise options)[55], or if they require additional assistance problem solving. For example, home visitors could help participants problem solve where to keep the home scale so they remember to use it weekly but to avoid younger children playing with. Or, if a participant sets a goal with the health coach to reduce intake of sugar-sweetened beverages, the home visitor can help them identify low/no-sugar beverage alternatives that are available in their local store.

12.2. Fidelity of the intervention

We will use methods similar to those used in complex, team-based behavioral interventions[82,83], to examine fidelity and the relationship with the outcome of PPWR. We will evaluate health coaching intervention fidelity and engage in an iterative quality assurance process. To ensure consistent approaches by health coaches, we will use "Coach Leader Guides" for each coach call (a detailed outline, i.e., review tracking information; review learning materials and discuss successes, barriers, goals). We will also randomly sample coach calls to audio record them for the intervention lead to review and monitor for fidelity. Coaches will ask permission to audio-record at the beginning of a given call and participants will be able to decline at any time. The audio recording will not be analyzed for research or published in any way. All audio recordings will be uploaded to a secure folder and destroyed when the study is completed.

We will ask participants if they would be willing to have a study team member contact them by phone or email when they have completed the health coaching intervention to get feedback on the program. This phone call will be optional and audio recorded if the participant gives permission. Participant feedback will be used to improve the health coaching program in the future.

13.0. Comparison group: Usual home visiting plus (mHIP-HV)**.** Upon randomization, women assigned to Usual Home Visiting Plus [maintain health in pregnancy (mHIP-HV)] will receive usual home visiting services, per agency guidelines and requirements. In addition, we will provide access to a brief video on maternal warning signs educational video that is available in English or Spanish. The video was developed for a home visiting client audience and is publicly available, https://mdmom.org/warningsigns. All home visitors, including those for participants in the Usual Home Visiting Plus Care group, will receive the same trainings, including content in Table 5.

14.0 DISCONTINUATION AND WITHDRAWAL OF PARTICIPANTS

Participants who discontinue the study early will be asked to complete remaining assessments at the time of discontinuation, if feasible and acceptable to the participant. All reasons for discontinuation will be documented clearly in study records

14.1. Discontinuation of study

An investigator may discontinue a participant from the study for the following reasons:

- Home visiting program staff, study investigators or Study Safety Officer does not think participation is in the participant's best interest or might be harmful;
- Significant study intervention non-compliance or disruptive behavior (e.g., argumentative with study staff or coach);
- Study is stopped;
- There may be other reasons to that we do not know at this time.

For pregnant women who experience a stillborn or intrauterine fetal demise, we will assess whether she would like to continue in the program, transitioning to the postpartum phase of data collection and/or intervention. Participants will not be discontinued if they choose to have baby adopted.

14.2. Withdrawal from Study

Participants who sign the informed consent form, and are randomized and subsequently withdraw, or are withdrawn or discontinued from the study, will not be replaced.

Participants are free to withdraw from participation in the study at any time upon request. They will be documented as: "withdrawn by participant" or "withdrawn by study PI". Data collected until the point of withdrawal can still be included in analysis, using the intention-to-treat (ITT)approach.

Participant withdrawal will be documented as a Protocol Event and reason will be documented as a NOTE TO FILE form.

14. DEFINITION OF PRIMARY AND SECONDARY OUTCOMES

14.1. Primary Outcome:

Postpartum weight retention at 6 months after delivery, defined as the difference between baseline weight (≤ 15 week gestation from medical records) and 6 month maternal weight (measured by cellularly enabled study scale) in pounds (lbs).

14.2 Maternal Secondary Outcomes

Gestational Weight Gain (GWG), defined as the difference between weight at 37-weeks postpartum (measured by cellularly enabled study scale) and pre-pregnancy weight (≤ 15 week gestation from medical records). Proportion who gain above the IOM recommended weight[84] will also be calculated.

14.3 Infant secondary outcomes

Infant growth outcomes of weight, length, and head circumference – at birth, 4 and 6 months – will be self-reported in surveys and will be verified using infant medical records.

14.4. Other outcomes including diet, physical activity, depression, stress, sleep and social support will be self-reported using online surveys created from standard survey instruments[85,86,87,57,80,81,72]

15. DATA ANALYSIS

15.1 General Approaches

Compare the effectiveness of the H42-HV program using a remotely-delivered health coaching intervention integrated into home visiting with mHIP-HV among 400 pregnant and postpartum women enrolled from early home visiting programs in Maryland:

- Primary outcome: PPWR at 6 months after delivery
- Maternal secondary outcomes: GWG (37 week minus baseline pregnancy [≤15 week gestation] weight); Proportion with excessive GWG.
- Infant secondary outcomes: Weight at birth, 2 months, 4months, and 6 months of age will be gathered as maternal self-report via online surveys and verified with infant medical records.
- Maternal and infant health care utilization, including receipt of postpartum care, ER visits and routine well infant visits, captured for those participants who are Medicaid recipients using claims data.
- Other outcomes: Maternal health behaviors (diet, physical activity, and breastfeeding); Maternal wellness (depression, sleep, and stress)

The main analyses for the primary and secondary outcomes will follow the ITT principle. The analysis for PPWR will utilize a mixed effects model to assess between group difference in mean of total PPWR.

15.2. Main analytic model for the primary outcome of PPWR (difference between pre-pregnancy weight and weight at 6 months postpartum).

We will carry out the main analysis to assess the between group difference using a mixed effects model characterized by a mean model relating the outcome to the predictors and a variance-covariance model addressing variance of all available longitudinal weight outcomes and correlation between outcomes measured overtime within individual. The predictors in the mean model will include a group indicator (0 for Group B and 1 for Group A), 3 visit indicators for 2, 4, and 6 months respectively, with 0 for baseline and 1 for the specific month postpartum the visit indicator corresponding to, and the group by visit interaction terms, adjusting for study sites, BMI category, and gestation at the time of enrollment used for randomization stratification, all as fixed effects. The regression coefficient of the group by 6-months postpartum weight interaction term will estimate the primary outcome, i.e., mean difference in PPWR at 6-months between intervention and control groups. We will use an unstructured variance-covariance model to allow full flexibility on outcome variances and correlations. Data from all participants randomized will be used in this analysis, including missing data which will be included using a software specified missing indicator.

15.3. Secondary outcomes and additional analyses

Analyses for between group differences in GWG and infant weights will be assessed using the same mixed-effects modeling approach with separate models similar to the main model described above. Between group differences in binary outcomes of diet, physical activity, breastfeeding and women's wellness outcomes (depression, sleep, stress, social support) will be described between H42-HV intervention and Control arms using standard cut points for the

scales and modeled using logistic regression model based longitudinal models implemented through generalized estimation equations (GEE) approach employing group indicator, visit indicators, group by visit interaction terms and adjusting for the variable used to stratified the randomization. Robust variance estimate will be used for statistical inferences to derive 95% confidence intervals for the population-average based estimates and corresponding p-values. Conforming to recommended maternal postpartum care utilization and well-baby care utilization over time will separately be modelled using similar GEE approach as described above for the longitudinal binary outcomes.

15.4. Exploratory analyses for heterogeneity of intervention effect

Importantly, we will explore for potential modifiers of intervention effects by conducting subgroup analyses by race/ethnicity, HV program characteristics, baseline BMI category (overweight/ obese), language spoken at home, low English proficiency, education level and exploring for effect modification by adding appropriate interaction terms to the primary mixed-effects model. Although we do not expect the main effects to differ, we will explore for the potential of such heterogeneity of intervention effect.

16.0. Sample Size and Power Estimates informing Primary Aim

We request approval for enrollment up to 400 participants with the goal of N=360 for power calculations.

Table 6. MDD for PPWR for sample of 360 with 90% power, after 30% random attrition

Power	SD of PPWR (Kg)	Minimum Detectable Difference (MDD) (Kg)
90%	5.5	2.26
90%	7.0	2.87
90%	8.0	3.28
90%	8.8	3.61

With this sample size, our objective is to determine the minimum detectable difference (MDD) for the primary outcome of PPWR between the 2 study groups. Our assumptions are as follows: Two-sided type I α error=0.05; type II β error=0.10; and 70% or greater follow-up for the main outcome of PPWR at 6-months. Based on our past experience and review of the literature, we anticipate <30% loss to follow-up for 6-month weights, consequential to drop-out of various kinds (e.g., lost to follow-up, censored due to new pregnancy). With this dropout rate and the assumption that the dropout is consistent with missing at random, we expect to retain an effective sample size of 252 participants for our primary outcome, by randomizing N=360 participants, with 126 participants in each arm. Standard deviations for the MDD evaluation were informed by previous studies of similar combined diet-physical activity behavioral interventions to limit weight gain in pregnancy and promote postpartum weight loss[88,89,90,91]. The MDDs range from 2.3- 3.6 kg with the assumption of 30% random attrition of the proposed sample size of 360. Based on these prior studies effect sizes we believe our sample size calculation in **Table 6** is conservative.

17. DATA MANAGEMENT

We will use REDCap, a secure, password protected, web-based application for building and managing online surveys and study data. We will ensure data quality through building cross-check, logic check, and range check for data entry and monitoring data collection completion through automatic flags in REDCap. The data manager will conduct thorough data checking and cleaning, including examining distributions and data patterns and running routine reports on run charts and outlier detection scripts, and flagging unusual data values and data inconsistencies for possible correction measures. We will also record and routinely review lag time in data entry, timely issue data queries on missing data, out of range values or illogical data relations and resolve identified data issues, and review types and distribution of data entry errors/issues and remedy any systematic concerns. Confirmed unusual data values and data inconsistencies will be reviewed and adjudicated by the study team to decide possible action and final decision made for any data correction will be documented. All data access and corrections get automatically logged in REDCap data audit trails.

The data manager will also prepare reports regularly for the PI, investigators, staff and the Safety Officer on Quality Control (see Data Safety and Monitoring Plan) for review and to remedy any concerns. Every effort will be made to determine the correctness of outlying values in a timely manner. Confirmed outliers will be flagged and set aside in the primary analysis. Outliers removed will generate a missing data code and be treated as for all other missing data. Sensitivity analyses will be conducted with inclusion of outliers to assess influence on results. The data manager and analyst will create detailed, organized documentation of variables and conduct analyses according to protocol under direction of Dr. Wang, study biostatistician.

18. DATA SAFETY AND MONITORING PLAN (DSMP)

We have included the DSMP in this IRB application. We will have a DSMB through the parent Center Grant, The Center for Cardiometabolic Health Equity.

19. DATA SECURITY PRIVACY AND PROCESSES

Our protocol was deemed Tier Risk A by the IRB Risk Calculator. We described Data Security and Processes below.

19.0. Data Storage and Analysis

We will store all Medicaid data extracts and all study data with PHI on the SAFE Desktop. We will use REDCap for data collection using surveys and management of study processes. All data analyses will be conducted on the SAFE Desktop. We will limit study staff access to the Desktop only for those who will require access and will remove access rights once this access is no longer required.

19.1. PHI Data on the Web-Based Platform and Study Scale

The web-based platform involves a “back end” build in REDCap, which contains all patient health information. Data from the at-home cellularly enabled study scale (BodyTrace or similar) will be integrated into REDCap using a secure API data transfer via a de-identified token. The user interface will be hosted internally within the Johns Hopkins firewall. We are working to re-create the educational platform and for this study it will be hosted and managed by Johns Hopkins Cloud & Virtualization Services and was developed by a large healthcare IT company called TonicGroup, Inc. It was selected because it has the optimal security measures in place to protect patient privacy. All data on the platform will reside behind the JH firewall. The platform uses standards for data exchange and integration, such as HL7 FHIR and is compliant with all U.S. privacy and security standards for electronic health records. With participant authorization (see above) the platform will integrate REDCap data using a secure API data transfer via a de-identified token. The summary data from the platform will be exported directly into the SAFE desktop.

Although a mobile application will be recommended for participants in the intervention group, no data will be directly transferred to the REDCap database; instead, participants will have the option of self-reporting their data using a unique encrypted REDCap link.

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