Remote lifestyle intervention to reduce postpartum weight retention: Protocol for a community-engaged hybrid type I effectiveness-implementation trial

Lindsay M Martin, Christine D McKinney, Lia Escobar Acosta, Janelle W Coughlin, Noelene K Jeffers, Alexandra Solano-Umaña, Kathryn A Carson, Wendy L Bennett, Kelly M Bower

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Abstract

Background: Maternal obesity is associated with significant racial disparities, with Black and Latina women at highest risk for related adverse short- and long-term health outcomes (e.g., hypertension in pregnancy, postpartum weight retention). Remote lifestyle interventions delivered during and after pregnancy hold promise for supporting healthy weight outcomes; however, few are tested in Black and Latina groups or address the neighborhood-level and psychosocial factors driving maternal health disparities. Implementing remote lifestyle interventions into community-based programs that serve birthing people may optimize trust and engagement, and promote scalability and sustainability to have a public health impact.

Objective: The goal of the trial described in this paper is to test the effectiveness of a culturally adapted remote lifestyle intervention (Healthy for Two-Home Visiting; H42-HV) implemented into home visiting compared with usual home visiting services (maintain Health in Pregnancy and Postpartum; mHIPP) on postpartum weight retention among Black and Latina pregnant/postpartum individuals. Facilitators and barriers to implementation of the intervention into home visiting will be examined.

Methods: We describe the rational and protocol for this hybrid type 1 effectiveness-implementation randomized clinical trial. In this paper we will highlight the community-engaged approach and trial design features that enable its implementation into home visiting and applicability of the intervention to the target population. Participants will be 360 pregnant individuals with overweight or obesity enrolled between 20-33 weeks gestation and randomized 1:1 to H42-HV vs. usual home visiting services. The primary outcome is weight retention at 6 months postpartum, calculated as 6-month postpartum weight minus earliest pregnancy weight (? 18 weeks gestation). Measures of implementation include intervention feasibility, acceptability, reach, adoption and fidelity. Throughout the paper we will highlight the community input used to improve intervention effectiveness and study implementation, and as a strategy to promote maternal health equity.

Results: This study was funded in June 2021 and recruitment began in April 2023. Data collection for the intervention effectiveness is expected to end in June 2026. Implementation evaluation is expected to conclude in December 2026.

Conclusions: This hybrid type I effectiveness-implementation randomized trial integrates a culturally adapted remote lifestyle intervention into early home visiting services to examine its effectiveness on postpartum weight retention compared to usual home visiting. We anticipate that the study results will enable an understanding of the drivers of successful implementation in a community-based setting to maximize future sustainability and dissemination of a strategy for reducing long-term obesity and other maternal health disparities. Clinical Trial: NCT05619705

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Keywords: pregnancy, obesity, postpartum weight retention, remote lifestyle intervention, home visiting, mHealth app, community-engaged research, implementation science, health disparities, maternal health

***Authors have made equally significant senior-level contributions to the work.**

Abstract

Background

Maternal obesity is associated with significant racial disparities, with Black and Latina women at highest risk for related adverse short- and long-term health outcomes (e.g., hypertension in pregnancy, postpartum weight retention). Remote lifestyle interventions delivered during and after pregnancy hold promise for supporting healthy weight outcomes; however, few are tested in Black and Latina groups or address the neighborhood-level and psychosocial factors driving maternal health disparities. Implementing remote lifestyle interventions into community-based programs that serve birthing people may optimize trust and engagement, and promote scalability and sustainability to have a public health impact.

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The goal of the trial described in this paper is to test the effectiveness of a culturally adapted remote lifestyle intervention (Healthy for Two-Home Visiting; H42-HV) implemented into home visiting compared with usual home visiting services (maintain Health in Pregnancy and Postpartum; mHIPP) on postpartum weight retention among Black and Latina pregnant/postpartum individuals. Facilitators and barriers to implementation of the intervention into home visiting will be examined.

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This study was funded in June 2021 and recruitment began in April 2023. Data collection for the intervention effectiveness is expected to end in June 2026. Implementation evaluation is expected to conclude in December 2026.

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This hybrid type I effectiveness-implementation randomized trial integrates a culturally adapted remote lifestyle intervention into early home visiting services to examine its effectiveness on postpartum weight retention compared to usual home visiting. We anticipate that the study results will enable an understanding of the drivers of successful implementation in a community-based setting to maximize future sustainability and dissemination of a strategy for reducing long-term obesity and other maternal health disparities.

Trial registration: The study was first registered at clinicaltrials.gov on 11/17/2022 (NCT05619705).

Introduction

Maternal obesity is a persistent public health concern with widening racial and ethnic inequities [1–3]. Up to 43% of Black and 37% of Latina reproductive-age people have overweight or obese status compared to 32% of White. [4]. Nearly 50% of these non-White individuals exceed recommended gestational weight gain (GWG) guidelines, contributing to adverse maternal and infant health outcomes (e.g., hypertension in pregnancy, preterm birth, and maternal mortality) [5–8]. It is imperative to focus public health prevention efforts on Black and Latina pregnant individuals who are most susceptible to worsening obesity (i.e., postpartum weight retention; PPWR) [9–12] and other long-term health problems, including cardiovascular disease [13–16]. Pregnancy offers an opportunity to initiate health and potentially sustain behavior change that limits GWG and its associated health risks because individuals are motivated to have a healthy baby [17]. This ideal window for health promotion extends to the period after birth when it is critical to sustain healthy changes and improve care transitions, especially among individuals with known barriers to healthcare access and quality [18]. These individuals have increased exposure to negative social determinants of health including environmental, financial, cultural and linguistic barriers, racism, limited health literacy, and inadequate insurance coverage, which impact postpartum visit attendance [19,20] and further exacerbate health risk [21–23].

Based on strong evidence, counseling and lifestyle interventions during and after pregnancy are a recommended and well-established strategy for limiting GWG [24–27] and reducing PPWR [28–31] and their implementation is being tested in real-world settings. For example, our team is testing a remote health coaching intervention to limit GWG integrated into prenatal care clinics [32,33]. However, there are several evidence gaps. First, few interventions have been tested in racial and ethnic minority groups [31,34], with especially low representation of Latina individuals [35]. Second, few interventions have been implemented and tested in community-based settings where high-risk pregnant and postpartum individuals access safety-net services. Finally, few interventions address health-constraining social factors that contribute to disparities in maternal health outcomes [30,36,37].

Importantly, implementing remote lifestyle interventions into community-based programs that pregnant individuals access and trust may optimize their benefits, promote scalability and sustainability, and have the broadest public health impact. Home visiting is an evidence-based public health strategy targeting high-risk pregnant individuals and families with children up to five years of age. Home visitors provide health education, promote positive parenting and early learning, and link

families with needed community resources and social support [38]. Early home visiting has been shown to prevent child abuse and neglect, improve maternal and child health, increase family socioeconomic position, and promote child development and school readiness [39]. Early home visiting is an ideal setting for delivering lifestyle interventions for pregnant and postpartum individuals because home visitors are uniquely positioned to address social and environmental factors impacting health behavior (e.g., neighborhood food availability and walkability) [38]. Recent randomized trials testing lifestyle interventions embedded in early home visiting services have shown lower GWG and PPWR up to 12 months, greater achievement of 5% weight loss, smaller waist circumference and reduced sugar-intake at 12 and 24 months [40], and greater success reducing access to sugar-sweetened beverages in the home up to 24 months [40,41].

The goals of this paper are to: 1) Describe the design of this hybrid type 1 effectiveness-implementation trial testing the effectiveness of the Healthy for Two-Home Visiting (H42-HV) remote intervention integrated into home visiting compared with usual home visiting services (maintain Health in Pregnancy and Postpartum[mHIPP]) on PPWR among Black and Latina pregnant/postpartum individuals; 2) Highlight the trial design features that enable its implementation into home visiting and applicability of the intervention to the target population; 3) Highlight application of a community-engaged approach to the conceptualization and design of the study to improve intervention effectiveness, study implementation, and as a strategy to promote maternal health equity.

Methods

This trial was funded as one of three studies in the Mid-Atlantic Center for Cardiometabolic Health Equity (MACCHE) NIMHD RFA-MD-21-007 Centers for Multiple Chronic Diseases Associated with Health Disparities: Prevention, Treatment, and Management (P50). We obtained IRB approval for this study protocol from the Johns Hopkins Medicine Institutional Review Board (IRB00307430). The protocol is registered in clinicaltrials.gov (NCT05619705).

Study design, aims and hypothesis

We designed this hybrid type 1 effectiveness-implementation randomized controlled trial starting mid- to late pregnancy (20 – 33 weeks) through 6-months postpartum to compare the effect of the H42-HV lifestyle intervention integrated into home visiting with usual home visiting services (mHIPP) among pregnant individuals with overweight or obesity. The primary outcome is PPWR

calculated as six-month postpartum weight minus pre-pregnancy [≤ 18 weeks gestation] weight. Additional measures of effectiveness include GWG and maternal health behaviors, wellness, and health care utilization. Our main hypothesis is that participants in the H42-HV arm will have lower PPWR compared to those in mHIPP.

Hybrid type 1 effectiveness-implementation trials assess the clinical effectiveness and implementation of the intervention to better understand barriers and facilitators to real world implementation to maximize future sustainability, advance the pathway from evidence translation into practice, and facilitate greater subsequent public health impact [42,43]. To that end, the study will also examine home visiting organizational factors that could impact the implementation of the intervention. We will use the Practical, Robust, Implementation and Sustainability (PRISM) framework [44] and domains from the Consolidated Framework for Implementation Research (CFIR) [45] to assess intervention feasibility, acceptability, reach, adoption and fidelity.

Application of a community engaged approach

We used a community-engaged research approach to inform the conceptualization and design of the study, including adaptation of H42-HV and its integration into early home visiting services. Using the "Continuum of Community Engagement in Research" [46], our level of engagement is best characterized as *community participation* because the community was actively engaged with a defined role in all stages of the research process. The study principal investigators (WB and KB) engaged home visiting stakeholders while developing the proposal and, once funded, employed a variety of strategies to establish and sustain two-way engagement, communication, and information sharing. All aspects of the study were enhanced by feedback from a diverse group of stakeholders including regional and state leaders in home visiting; participating home visiting program managers and home visitors; and current or recently pregnant Latina and Black individuals participating in home visiting services.

During the conceptualization phase, we met with state and program leaders to gather information about the relevance of the intervention and alignment with state and program public health priorities. We also explored the feasibility and acceptability of implementing the intervention within the home visiting setting. In the planning phase of the study, we established a translation and cultural adaptation team of primarily native Spanish-speaking maternal and child health professionals (i.e., dietician, midwife, nurse) and health professional students (i.e., nursing and medicine) to adapt the H42-HV intervention for Spanish-speaking participants.

Once funded we established a Coordinating Council with home visitors, leaders from participating programs and Spanish and English-speaking community members. Regular meetings with the Coordinating Council informed all aspects of the study protocol and implementation measures, recruitment processes, intervention adaptation and safety protocols. We asked for specific feedback about referral process, recruitment materials (flyers, videos), intervention approach and messaging, cultural adaptability, and community resource needs through semi-structured one-on-one interviews (six with home visiting program leaders, seven with Coordinating Council members). We conducted end-user testing of the H42-HV mHealth app (Figure 1; six with parents and two with home visitors).

Overall, the feedback highlighted barriers and facilitators to integration of H42-HV into home visiting programs and identified strategies for recruitment, adaptations to meet the language and cultural needs of Latina and Black individuals, and effective coordination between the home visitor and health coach. We describe how we addressed feedback from the Coordinating Council and the additional stakeholders in each of the sections below.

Participant setting

In the formative phase of the trial, we engaged with seven home visiting programs from across five counties in Maryland that serve predominantly non-Hispanic Black and/or Latina, English and Spanish-speaking pregnant individuals with low incomes and literacy levels. Once we launched recruitment, we invited additional early home visiting programs to refer participants to be screened and enrolled in the study. We did not restrict to a particular model of home visiting and included evidence-based and non-evidence-based models [38]. For example, partnering home visiting models include but are not limited to, Healthy Families America, Healthy Start, Nurse Family Partnership, and Babies Born Healthy. Depending on the model, home visitors are either nurses or paraprofessionals. Participating home visiting models enroll families as early as pregnancy and follow them six months to five years postpartum, but the frequency and intensity of home visits varies by model.

Participant eligibility

As an effectiveness trial, we apply the broadest eligibility criteria to enhance generalizability: 18 years of age or older, singleton pregnancy between 20 and 33 weeks gestation, and planning to enroll in home visiting services at one of the study's participating sites. We are focusing this study on

individuals who are overweight or obese (BMI ≥ 25.0 kg/m^2) prior to pregnancy as they are at highest risk for future cardiometabolic disease. See Textbox 1 for additional eligibility criteria.

Textbox 1. Eligibility criteria.

Inclusion criteria

- Age ≥ 18 years
- Singleton pregnancy, 20 – 33 weeks gestation
- 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
- Intention to enroll in early home visiting services at a participating site
- Completion of screening and baseline data collection
- Willing to participate in the intervention and data collection procedures (e.g., home weights)

Exclusion criteria

- Age <18 years
- Type 1 diabetes
- < 20 weeks gestation or > 33 weeks gestation
- Pregnant with multiple fetuses
- Advised not to engage in exercise by medical provider
- Not cleared by the study's clinicians or home visiting program staff
- Planning to relocate outside of Maryland in the next year
- Active substance abuse (except marijuana)
- Psychiatric or substance use-related hospitalization in the past year
- Active eating disorder

Evidence shows that starting an intervention early in pregnancy has the greatest impact on pregnancy outcomes and GWG [47,48]. However, many home visiting programs rely on several steps to occur before services can begin, i.e., entry in prenatal care, referrals from clinic, screening by outside agency for eligibility, and outreach by home visiting program. Based on input from participating home visiting programs, we selected a broad enrollment window during pregnancy (20-33 weeks gestation) and will continue intervention delivery through six months postpartum. Given state and program leader feedback about the potential for home visiting enrollment in late pregnancy, we selected the primary outcome as return to pre-pregnancy weight or below, since postpartum weight retention is a risk factor for future obesity.

Screening and recruitment

With feedback from home visiting program partners (see Application of a community-engaged approach) we designed the role of home visitors to be low-touch and aligned with the procedures they already use in their program and visits. Figure 2 outlines the study design and recruitment procedures. Home visiting staff inform potentially eligible clients about the study via conversation, e-mail or text message using a 'toolkit' of different materials available in English and Spanish to accommodate program, staff and client needs and preferences (e.g., suggested dialogue, paper flyers/postcards, 2-3 min informational video). All recruitment materials include a link and QR code to an "e-Interest form" (to be completed by clients or home visitors on their behalf) which requests basic eligibility information to preemptively exclude clients < 18 years old and > 33 weeks gestation, and additional details to facilitate next steps of the screening process.

Upon receiving a completed "e-Interest form," research staff reach out via phone to further assess interest and screen for eligibility, then complete a phone-assisted e-consent which includes a signed authorization for medical record release of prenatal and infant records and claims data. Following consent, study staff immediately request prenatal clinic records for height and pre-pregnancy weight to confirm BMI criteria and participants complete online or phone-assisted baseline data collection surveys. Once these steps are complete, consented participants meet virtually with staff for a video-facilitated randomization (i.e., enrollment) visit. At randomization participants receive instructions for taking home weight measurements using a study-provided smart scale shipped to their home; intervention participants are oriented to the app and provided the name of their health coach. In

response to home visitors' interest in the result of each client they refer (i.e., ineligible, unable to reach, enrolled), we provide them with the option to 'opt in' to live email updates on referral outcomes.

Randomization and blinding

Three hundred and sixty participants will be randomized 1:1 to H42-HV or the mHIPP comparator arm. Randomization is stratified by home visiting program region + primary language served (i.e., central-Spanish/English, capital-Spanish/English, eastern-Spanish/English, southern-Spanish/English, western-Spanish/English) and BMI (BMI ≥30 kg/m^2 vs. 25-30 kg/m^2), and within each stratum using randomly varying block sizes of 2, 4, and 6. The randomization scheme was generated using STATA and imported into REDCap [49,50]. Assignment remains unknown until a participant is enrolled. Due to the nature of the lifestyle intervention, participants, home visitors and the intervention team and safety monitor will not be blinded to randomization assignment. Until the end of the trial all non-intervention study staff and co-investigators, including the principal investigators and data collectors, will remain blinded, except the lead biostatistician.

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

The intervention was adapted from our previously designed and pilot tested remotely-delivered lifestyle intervention (called Healthy for Two/Healthy for You) to limit GWG and PPWR in a racially-diverse population with low literacy [32,33]. The person-centered intervention uses a standard behavioral approach to weight management [51], teaching strategies aligned with Social Cognitive Theory such as self-monitoring, goal setting and problem-solving [52]. The overarching goal of the H42-HV intervention is for participants to have lower PPWR six months after delivery.

Intervention components and adaptations

We used an iterative approach for translating and adapting intervention content and technologies using feedback from our key stakeholders (described under "Application of a community-engaged approach"). In addition to shifting intervention timing and focus to the postpartum period, we reframed messaging about program goals to achieving "overall health and wellness" versus a "healthy weight." Consistent early feedback from home visitors suggested strong internalized weight biases among their clients may impact intervention engagement and acceptability. Weight stigma is pervasive in health care settings, has detrimental impacts on overall health and utilization of healthcare services

[53,54], and has more recently been regarded as a social determinant of poor birth outcomes [55]. Table 1 summarizes the adapted components of H42-HV.

Table 1. H42-HV Intervention description and approach.

Intervention Components	Description/Frequency
Person-centered health coaching (English or Spanish)	• 10 total phone or video ~30 minute meetings using a person-centered approach (4 pregnancy, 6 postpartum), plus 2 as needed "boosters" • Starts between 20 and 33 weeks gestation through 6 months postpartum • Coaches have access to a mHealth coaching interface to view participant app engagement and health progress (see "Interactive mHealth app")
Self-weighing via home smart scale	• Participants self-weigh at least once weekly on cellular-enabled home smart scale • Paper and electronic "wellness journal" available to self-monitor diet and exercise
Interactive mHealth app	Hosts web-based learning and goal setting activities, smart scale weight displays, two-way participant-coach messaging; promotes engagement via dynamic in-app messages and email reminders
Learning activities	10 educational, interactive modules focused on diet, exercise, social support, stress, mood and sleep. Educational methods include: • Simple, brief education on core topic • Audio quotes from 3 ethnically-diverse moms describing personal challenges/successes and behavioral strategies that help them meet health and wellness goals • Optional content quizzes: 5 simple multiple-choice questions to reinforce key concepts • Opportunities to reflect/share: Open-ended free-text questions (ranging from 4-9 total per learning activity) to promote goal-oriented thinking, problem-solving, and identification of barriers and successes
Add-on learning	• Videos and external links covering topics such as breastfeeding, gestational diabetes, and smoking cessation.

Interactive SMART goal setting	• Interactive tool that aids participants in setting their own SMART goals and rating progress
Weight display	• Real-time view of home smart scale weights with feedback to support goal of returning to pre-pregnancy weight
Coach-participant messaging	• Synchronous communication stream primarily used for scheduling and delivery of individualized intervention content, i.e., PDFs, images, etc.
Homepage	• Personalized summary to facilitate intervention adherence (i.e., date/time of upcoming coach meetings, most recent coach message, reminders to weigh) and engagement (i.e., seasonal health or wellness "Tip of the week")
Coach/Coach manager interface	• Coach interface with dynamic access to participant weight data and engagement with app (i.e., SMART goals, free-text entries, etc.) • Coach manager interface with real-time access to participant and group-level data for individualized case management and ongoing support and management of all coaches

SMART = specific, measurable, achievable, relevant, time-length

Person-centered health coaching

The cornerstone of H42-HV is *health coaching* using an evidence-based person-centered approach [56] aimed at enhancing participants' intrinsic drive to make health-related behavior changes (diet, exercise, stress management). Participants have up to 12 coach meetings (10 planned plus two as needed "boosters") via video or phone when they join the study (between 20-33 weeks gestation) through 6 months postpartum (~4 biweekly during pregnancy and ~6 monthly postpartum). The frequency of coach meetings is consistent with similar interventions showing an effect on postpartum weight retention [28,32,57] and based on evidence that moderate (i.e., >=6 contacts) to high-intensity (i.e., >=12 contacts) lifestyle interventions have the greatest effect on GWG [25,58]. Coaches receive enhanced training on weight bias and cultural sensitivity and supporting behavioral changes in the context of common social and environmental barriers such as food insecurity and neighborhood safety.

Health behavior tracking (Self-weighing via home smart scale)

Participants are instructed to weigh weekly on a *home cellular-enabled smart scale* called BodyTrace [59] that transmits live data to the H42 mHealth app and coach interface described in detail below. Coaches emphasize that self-weighing is a core tool to assess progress, similar to monitoring

one's exercise minutes and the type/amount of food and drinks consumed. Participants have the option to track and share diet and exercise behaviors with their coach as well as daily ratings of their mood and sleep using a simple paper "wellness journal" or "e-wellness journal" delivered daily or weekly via SMS or email.

Interactive Healthy for Two mHealth app (H42 mHealth app)

Our team designed the *interactive mHealth app + coach interface* (Figure 1) based on intervention content tested in past trials [32,33]. The H42 mHealth app is accessible via mobile phone and delivers education at a < 6th-grade reading level [60–62] via interactive learning activities that provide guidance on making healthy lifestyle changes in the context of common environmental barriers, e.g., eating healthy on a budget, low-cost ways to manage stress. The mHealth app contains an interactive SMART goal setting activity, facilitates two-way participant-coach communication, displays smart scale data, and promotes adherence and engagement via dynamic in-app messages and email reminders (1). End-user testing completed in preparation for the trial (three Spanish-speaking, five English-speaking current or recently pregnant users) generated reactions to app design and images, usability, interactive functionality, cultural appropriateness and effectiveness. Consistent feedback gathered and addressed include: a preference for a brighter color palette; more images and less text/numbers; more traditional Latino food options; larger-sized body types; simpler graphics (i.e., bar versus line graph), and a stronger representation of family (i.e., households with multiple children). If cost is a barrier we subsidize online access (e.g., data cards).

The *coach/coach manager interface* provides dynamic access to participant smart scale weights and app activity (i.e., goals, free-text responses) and food and exercise data for those who choose to track these behaviors using the "e-wellness journal" that syncs data to the interface. The interface additionally serves as a documentation and scheduling tool. A coach manager interface provides individual and aggregate summary data to facilitate regular participant oversight, ongoing support and management of coaches and intervention adherence monitoring throughout the study.

Usual Home Visiting Plus care comparison: Maintain Health in Pregnancy and Postpartum (mHIPP)

Participants randomly assigned to Usual Home Visiting Plus (maintain health in pregnancy and postpartum; mHIPP) receive usual home visiting services, per agency guidelines and requirements. In addition, we provide access to a brief educational video on urgent maternal warning signs, available in

English or Spanish. The video was developed for another project involving a home visiting client audience [63,64] and is publicly available, https://mdmom.org/warningsigns. Private, staff-monitored Facebook groups are offered to disseminate information on healthy pregnancy and allow for community building and retention for both groups (mHIPP and H42-HV). Both groups are also provide county-specific resource lists with information on green spaces, food banks, mental health resources, medical centers, and intimate partner violence support. This resource list is available as an e-map (using Google maps) and paper version.

NIMHD research framework adaptation for H42-HV

We adapted the National Institute on Minority Health and Health Disparities (NIMHD) research framework [65] to depict the multi-level influences (individual-, interpersonal-, community-, and societal-level) embedding the remote intervention into early home visiting services has on health outcomes and disparities, including social determinants of health (Figure 3). The H42-HV intervention impacts *individual-level* factors by promoting healthy lifestyle in women with cardiovascular risk factors, regardless of insurance coverage or health literacy. While coaches provide education and strategies for making healthy changes (i.e., adding fruits and vegetables), home visitors address context-specific barriers (e.g., healthy food availability) and leverage context-specific assets (e.g., local food banks) to increase success at achieving behavioral goals. At the *interpersonal-level*, home visitors provide social support and connect participants with social support networks that promote healthy lifestyle and tools to navigate family/peer norms; health coaches teach participants effective communication skills to strengthen the support they receive from their existing network (e.g., home visitor, health care providers, family and peers) and tailor it towards making healthy changes. The H42-HV intervention addresses *community*- and *societal-level* influences by connecting participants with local resources and promoting parent and infant utilization of healthcare services (e.g., postpartum care, primary care). Ultimately, the study is designed to promote a holistic approach to reducing cardiometabolic health inequities among birthing people.

Data collection and data sources

Effectiveness measures and methods

Table 2 summarizes methods of measurement and timing aimed at improving access, retention and minimizing participant burden (also see Figure 4). Early conversations with home visiting program

leaders indicated that home visitors would not have time to collect study data; therefore, data collection procedures were designed to not involve home visitors. Data are collected using four methods: a cellular-enabled home smart scale, medical record review, online surveys via REDCap and Medicaid claims data.

Table 2. Schedule of intervention effectiveness and safety measures

Measure	Pregnancy			Postpartum		
	BL[a]	37 wk.	Delivery[b]	2 mo.	4 mo.	6 mo.
Maternal weight and height prenatal clinic medical records	MR review[c]	Smart scale		Smart scale	Smart scale	Smart scale
Labor and delivery discharge summary from outside hospitals			MR review			
Infant weight and length from pediatric practices			MR review[d]			
Online Surveys						
Demographics and medical history [66–69]	✓		✓[e]			
Dietary behaviors (DSQ) [70]	✓					✓
Physical activity (IPAQ-SF) [71]	✓			✓		✓
Depression and anxiety (EPDS) [72]	✓		✓	✓	✓	✓
Brief Perceived Stress Scale (PSS-4) [73]	✓			✓	✓	✓
Brief Pittsburgh Sleep Quality Index (B-PSQI) [74]	✓			✓	✓	✓
Functional Social Support Questionnaire (FSSQ) [75]	✓			✓		✓
Social determinants of health [67,69]	✓					
Experiences of discrimination (MDR) [76]	✓					
Tobacco, marijuana and alcohol (PRAMS) [77]	✓					✓
Pregnancy intention (PRAMS) [77]	✓					
Usual source of (maternal) care (PRAMS) [77]	✓					✓

Experiences with care (PRAMS) [77]	✓			
Infant care (PRAMS) [77]	✓	✓		
Postpartum visit attendance and support (PRAMS) [77]			✓	
Postpartum contraception (PRAMS) [77]			✓	✓
Breastfeeding intention and practices [77,78]		✓	✓	✓
Use of community and safety net services - WIC[f] (PRAMS) [77]		✓	✓	✓
Engagement with home visiting		✓	✓	✓
Safety survey	✓	✓	✓	✓
Medicaid Claims				
Maternal and infant health care utilization		✓	✓	✓
Home visiting utilization and safety net services		✓	✓	✓

[a] Baseline window = 20 - 33 wks. gestation; [b] Delivery through 2 wks. postpartum; [c] First prenatal weight documented in EMR up to 18 weeks; [d] Self-report infant weight and length also collected; [e] Infant race and ethnicity collected at delivery
Abbreviations: BL = baseline; Wk = weeks; Mo = months; EMR = electronic medical record; WIC = women, infants and children

Assessment and verification of maternal weight using a smart scale

Smart scale weights are collected at four time-points: 37-weeks gestation, and two-, four-, and six-months postpartum (see Table 2). Participants are instructed to weigh themselves in light indoor clothes without shoes on their home smart scale (BodyTrace [59]). The BodyTrace smart scale transmits data to the study team via cellular connectivity (no WiFi or cellular plan required), which is ideal for rural client communities with intermittent Wifi or those with reduced access to cellular data or inconsistent data plans. The BodyTrace smart scale was selected because it demonstrates good concordance with in-person assessments [79,80] and has been used in several large weight management trials [81,82], including those with racially-diverse populations with low literacy and income levels [83–85]. The scale is mailed to participants' homes after randomization and brief text reminders to weigh occur at each study assessment timepoint (i.e., "Time to step on your scale"). Staff monitor weight data transmitted to the study's REDCap server in real-time and reach out to participants with no weight by the middle of each designated assessment "window," which ranges +/- 10 days for all study time-points. Staff also monitor battery power and strength of cellular connection to assist participants

with related issues, as needed. To mitigate the disruption environmental factors (e.g., potential for multiple users or scale displacement) have on data quality, we programmed a dynamic weight cleaning procedure that requires participants to confirm questionable weights by responding to a one-question survey sent via text message. For intervention participants, this cleaning procedure assures real-time accuracy of weight graphs in the H42 mHealth app, as well as automated reminders, including in-app messages that prompt participants to weigh if a valid/confirmed weight is not available after seven days. After 14 days, coaches are notified to make a personalized outreach reminding participants to weigh.

Obtaining medical records and abstracting information on pre-pregnancy weight

Participants consent to pre- and postnatal medical record release for themselves and their infant prior to pregnancy through one year postpartum (see Table 2). We use a secure electronic fax system (OpenText RightFax) to request medical records from prenatal clinics, offices and hospitals. “Pre-pregnancy” weight is defined as the earliest measured weight obtained from medical records up to 18 weeks gestation; when not available, we use self-reported weight. We also abstract height, parity, and comorbid conditions from medical records.

Online questionnaires

We used REDCap to build and design online questionnaires using standard instruments selected to minimize participant burden and enable completion at home (see Table 2).

Demographics and social determinants of health

Maternal and infant demographics and social determinants of health are collected using standard questions from the PhenX toolkit [69], 2020 US Census Informational Questionnaire [66] and Accountable Health Communities Health-Related Social Needs screening tool (AHC HRSN) [68]. Additional common data elements related to participant characteristics and social determinants of health were incorporated as required by the Health Equity and Action Network for data harmonization at the NIH Multiple Chronic Diseases Disparities Research Consortium [67]. Experiences with discrimination are measured using the Everyday Discrimination Scale [76].

Maternal health behaviors, attitudes and experiences

Dietary intake and exercise are assessed using the Dietary Screener Questionnaire (DSQ) [70] and International Physical Activity Questionnaire - Short Form (IPAQ-SF) [71], and measures of wellness (mood, stress, sleep quality and social support) include the Edinburgh Postpartum Depression Scale (EPDS) [72], Brief Perceived Stress Scale (BPSS-4) [73], Brief Pittsburgh Sleep Quality Index (B-PSQI) [74] and Duke-UNC Functional Social Support Questionnaire (FSSQ) [75], respectively. Several questions from the standard and core measures of the Pregnancy Risk Assessment Monitoring System (PRAMS) [77] assess pregnancy and breastfeeding intentions and practices, contraception, substance use (tobacco, marijuana and alcohol), and experiences with/use of health care before and after birth.

Infant health, sources of care and feeding practices

Infant overall health, feeding and sources of care are assessed using the PRAMS [77] and Infant Feeding Practices Survey [78]. Use of community and safety net programs (i.e., Supplemental Nutrition Program for Women, Infants, and Children, Supplemental Nutrition Program) are also measured using the PRAMS [77].

Engagement with home visiting services

Engagement in home visiting services and frequency of contacts with home visitors will be collected at all postpartum timepoints to assess "dose" of home visiting during the study.

Intervention Satisfaction

Intervention participants complete a satisfaction survey at the end of the study using an adapted survey tool administered and reported on in previous trials [32,33].

Medicaid claims data

We will request Maryland Medicaid claims data for all consented participants with Medicaid to assess maternal and infant healthcare utilization outcomes (i.e., attendance at prenatal care visits, postpartum visit, primary care visits, infant visits, receipt of infant vaccines) via a data use agreement with the Maryland Department of Health (Table 2).

Implementation process measures and methods

Measures to evaluate implementation are based on a combined framework of PRISM [86] and domains from the CFIR [45]. Table 3 outlines all implementation outcomes and measures.

Table 3. Implementation process measures and methods

PRISM + CFIR Area	Implementation Process Measure	Data Collection Method (Pre, During, Post-Trial)
Organizational perspectives	HV program perceived usability, adaptability and relative priority of the intervention	Surveys before/after program orientation; Focus groups post-trial
Organizational characteristics (Inner setting from CFIR)	HV program culture, management support and cooperation, systems, training, staffing and incentives	HV leader surveys pre-trial
External environment (Outer setting from CFIR)	HV program regulatory environment (policies and incentives); Patient needs and resources	HV leader surveys pre-trial; County reports; Census and county rankings database
Reach	Total # clients enrolled out of those screened and eligible; Total # clients enrolled out of new pregnant clients enrolled in HV	Study recruitment and enrollment data; HV leader surveys post-trial
Implementation (Engaging/ reflecting/ evaluating process from CFIR)	Engagement of program leaders in implementation process; Qualitative feedback on progress and quality of implementation	Coordinating council, formative interviews with home visiting program leaders, focus groups, and research team discussion and reflection throughout trial
Adoption	Proportion of sites across state that opt to participate in study; Adoption of training, recruitment procedures; and level of involvement supporting intervention participants	Home visiting staff focus groups post-trial; Review of study recruitment and enrollment data
Fidelity of the intervention (Coach and participant)	Coach adherence to meeting guides and patient-centered approach; Participant adherence to intervention components and perceived acceptability	Review of audio recorded coach meetings during trial; Reports from data management systems, Participant acceptability survey post-intervention

Abbreviations: PRISM = practical, robust, implementation and sustainability; CFIR = consolidated framework for implementation research; [3]HV=home visiting

Organizational perspectives

To support state and program leader feedback gathered during conceptualization phase of the study (see *Application of a community-engaged approach*), home visitors' perspectives of the intervention were assessed via survey before and after a one-hour study staff-led orientation (overview of study goals, design and referral procedures) they received pre-trial. They rated the importance of and need for resources to address various health-related topics (i.e., nutrition, exercise) with their clients before the training and after they rated intervention acceptability, appropriateness and feasibility [87]. At the end of the study, we will conduct two focus groups with home visitors from participating programs to further explore perceived usability, acceptability and adoption of the intervention. Interview guides will be developed using the PRISM framework [86] and include questions assessing barriers and facilitators to implementation.

Organizational characteristics (inner setting)

Features of home visiting programs through which the implementation process will proceed and that may support or impede their ability to successfully implement the intervention (e.g., structure, enrollment, staffing, service modality, and curriculum) were assessed pre-trial using a survey completed by home visiting program leaders.

External environment (outer setting)

The county-level economic, political and social context within which the home visiting programs reside and that may affect their ability to successfully implement the intervention (e.g., social determinants of health, obesity rates, demographics, reimbursements, health and wellness resources) will be assessed pre-trial using a survey completed by home visiting program leaders and publicly-available data from county reports, US Census Bureau data [66], and a county rankings database [88].

Study reach

We will quantify study reach as: 1) the total number of clients enrolled in the study out of new pregnant clients enrolled in home visiting and; 2) the total number of clients enrolled in the study out of those screened and eligible for the study.

Implementation (Engaging, reflecting, evaluating)

We will measure implementation through a combined strategy of gathering feedback from home visiting programs about the progress and quality of the implementation and holding regular debriefings with personnel and team about progress and experience.

Adoption of intervention

We will track the proportion of home visiting sites across the state that opt to participate in the study and assess level of involvement in study procedures and the intervention via survey and home visitor focus groups post-trial.

Fidelity of the intervention: Coach and participant adherence (during/post-intervention)

We will examine intervention fidelity and its impact on the primary outcome using common procedures applied in multi-component remote lifestyle intervention trials [89,90]. Health coach fidelity to a participant-centered approach and standard meeting components (e.g., reviewing successes and progress, setting goals) will be measured using an iterative quality assurance process of sampling and reviewing audio-recorded coach meetings. We will track participant adherence to each component of the intervention (coach meetings, mHealth app and smart scale use) and intervention acceptability using an end-of-study survey.

Retention strategies for participants

Based on our experience recruiting and retaining pregnant women, we will use several methods to achieve high retention, including rapport-building, sending birthday and birth cards, and using email and text message reminders based on participant's preferred method of contact. Participants will be provided gift cards after each data collection visit: $10 at enrollment; $10 at 37-weeks, $15 at 2 weeks postpartum, and $20, $25 and $30 at two, four, and six months postpartum, respectively (see Figure 4). Since participants will be engaged in home visiting and consider the program part of their care, we anticipate low risk for loss to follow-up.

Methods for ongoing home visitor and community engagement

Home visitor engagement will involve monthly recruitment updates to sites and site supervisors, raffle incentives, ongoing training opportunities on topics of interest and brief one-on-one

"check-ins" between a study team member and home visitor "site champion" aimed at quickly mitigating concerns or struggles pertaining to study procedures. Community engagement throughout the trial will involve quarterly newsletters to all stakeholders (i.e., coordinating council, state-level leaders) including home visitor and community member "spotlights" and participant success stories. Additional incentives will include an annual financial incentive to each home visiting site.

Analytic approach

Sample size and power estimates

With 360 participants our objective is to determine the minimum detectable difference (MDD) for the primary outcome of PPWR between the two study groups. Our assumptions are as follows: Two-sided type I error=0.05; type II error=0.10; and 70% or greater follow-up for the main outcome of PPWR at six months. Based on past experience [91] and the published literature, we anticipate < 30% loss to follow-up for six-month weights, consequential to drop-out of various kinds (e.g., lost to follow-up). With this dropout rate and the assumption that the dropout is consistent with missing at random, we expect to randomize N=360 participants (n=180 per arm) to retain an effective sample size of 252 participants (126 participants in each arm) for our primary outcome. Standard deviations for the MDD evaluation were informed by previous studies of similar combined diet-exercise lifestyle interventions to limit weight gain in pregnancy and promote postpartum weight loss [25,40,92,93]. The MDDs range from 2.3- 3.6 kg with corresponding SDs for PPWR between 5.5 and 8.8 kg with the assumption of 30% random attrition of the proposed sample size of 360.

Main analytic model for the primary outcome of postpartum weight retention

The main analysis will assess the between group difference in PPWR (difference between earliest pregnancy weight and weight at 6 months postpartum) 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), three visit indicators for two, four, and six months respectively, with 0 for baseline and 1 for the specific month postpartum the visit indicator corresponds to and the group by visit interaction terms, adjusting for study sites (region/primary language served),

BMI category, and gestation at the time of enrollment used for randomization stratification, all as fixed effects. The regression coefficient of the group by six 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 randomized participants will be used in this analysis, including missing data which will be included using a software specified missing indicator.

Secondary outcomes and additional analyses

Analyses for between group differences in GWG (defined as the difference between weight at 37-weeks pregnancy and pre-pregnancy weight) 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, exercise, breastfeeding and women's wellness (depression, sleep, stress, social support) will be described between H42-HV and mHIPP 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 stratify 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.

Exploratory analyses for heterogeneity of intervention effect

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

Safety surveillance and monitoring

For active surveillance, a safety medical officer will oversee the review of medical records post-delivery from labor and delivery and infant discharge summaries. We will administer safety surveys after delivery and at two, four and six months postpartum to enable tracking for all maternal and infant hospitalizations, emergency room (ER) visits and labor and delivery triage evaluations (Table 2). We created protocol to alert the team and manage high levels of depressive symptoms or interpersonal violence (Table 2). The study has an IRB, a sponsor-approved Data Safety and Monitoring Plan, and oversight from the Mid-Atlantic Center for Cardiometabolic Health Equity (MACCHE) Data and Safety Monitoring Board that meets twice a year to review study progress, intervention adherence and adverse events (mild, moderate, severe).

Discussion

We designed this hybrid type 1 effectiveness-implementation randomized controlled trial to test a remote lifestyle intervention for weight management during pregnancy and postpartum in a community-based setting among non-Hispanic Black and Latina individuals that experience health disparities. Early home visiting programs hold promise to be an ideal setting to integrate lifestyle interventions because of their unique ability to address relevant social and environmental conditions impeding healthy behaviors (i.e., access to healthy foods, and transportation), as well as support and improve transitions to postpartum care. The goal of this hybrid trial is to evaluate the effectiveness of a newly adapted remote lifestyle intervention (H42-HV) and effectively integrate the intervention into early home visiting services to reduce PPWR. The study methods will enable the gathering of important data about the facilitators and barriers to implementation of the intervention in the early home visiting setting and for this vulnerable population.

A major strength of the trial's design is the community-engaged approach, which started in the grant conceptualization and pre-implementation phases to inform project design. Community-engaged research approaches have increased dramatically in the last few decades and are linked with statistically positive outcomes and success recruiting and retaining racially and ethnically-diverse marginalized populations [94–96]. Community-engaged research has many benefits, including ensuring intervention appropriateness, acceptability and applicability [97–100], ensuring study methods and intervention are properly adapted to the population of interest [99,101,102], and promoting trust, transparency and bi-directional learning between research teams and stakeholders [97,103,104]. Adopting this approach has

already guided key research design decisions including: 1) containing the primary role of home visitors to recruitment of study participants to minimize impact on workflow; 2) enrolling participants mid to late-pregnancy (20-33 weeks) to align with client enrollment in home visiting programs; 3) defining primary outcome as weight retention at six months postpartum to allow time for increased support during the postpartum period and; 4) focusing study goals and messaging on achieving "overall health and wellness" versus a "healthy weight" to minimize the effects weight bias internalization may have on recruitment and intervention acceptability. Employing remote data collection procedures was another important design consideration (i.e., smart scale, access to prenatal medical records) given the distance to rural locations and transportation barriers of home visiting clients, as well as anticipated challenges they might have reporting their height and/or weight to confirm eligibility - a challenge confirmed soon after study launch. We anticipate that the continuation of our Coordinating Council and other methods of community engagement will drive future decisions about interpretation of data and dissemination of findings.

The iterative process of end-user interviews that informed the design, features and functionality of the H42 mHealth app was especially valuable for adapting and improving it, including methods for incorporating weight goals and progress (i.e., simple, colorful graph versus weight change statistics) and translating the interactive goal setting activity for Spanish-speaking participants. Comprehensive measures of adherence to coaching, the H42 mHealth app and the smart scale are a major strength of the study given the growing complexity of remote lifestyle intervention packages and the critical need to differentiate the effects of unique components [26]. Similarly, access to robust engagement metrics for distinct mHealth app features (i.e., interactive goal setting, coach messaging, access to weight data, comprehension quizzes, educational videos) may build upon patterns of website engagement characterized by Power et al [105] in a low-income Latina sample; of note in this study, website engagement was a strong predictor of weight retention at six months postpartum.

The design of the study has limitations that could impact its interpretation of results. First, control participants will have access to a scale for data collection, and regular self-weighing is a key component of behavioral weight management [51]. From a health equity and ethical perspective, we decided that we would refrain from instructing control participants not to weigh themselves outside of data collection and instead, statistically control for number of measured weights across groups. Nonetheless, given the enhanced level of engagement intervention participants will have around self-weighing (i.e., reminders, ability to view progress on app and feedback from coach), we expect the

frequency of weighing in the control group to be significantly lower, and frequency is the strongest known predictor of overall weight change [106]. Another limitation is our limited ability to formally measure and control for the varying levels of support that the home visitors offer clients throughout the trial, which may differentially impact behavior change (e.g., addressing access to healthy food, discussing healthy lifestyle). This lack of control precludes our ability to measure intervention effectiveness for a high-risk, Black and Latina, English and Spanish-speaking sample outside of the context of home visiting. Although home visitors were intentionally removed from intervention delivery, early feedback conveyed a preference among some home visitors to be actively involved, i.e., ability to access SMART goals (assuming clients' permission). The differences in home visitor training, i.e., nurse vs paraprofessional, curriculum and intensity of home visiting models in the trial, i.e., frequency of visits range from weekly to two total during the first six months postpartum, may also differentially impact client success. We expect qualitative data on intervention adoption captured in focus groups post-trial to enhance our understanding of the potential role home visitors play moderating intervention effects and will leverage these insights for future trial designs and intervention adaptions.

Conclusion

There is a critical need to develop effective lifestyle interventions for Black and Latina pregnant and postpartum people who experience the greatest risk for adverse pregnancy outcomes. This study has the potential to provide a high-quality assessment of the effectiveness of a remote lifestyle intervention for a Black and Latina high-risk population and highlight facilitators and barriers of its implementation in a grounded service strategy specifically geared towards improving maternal and infant health. We expect results to yield important findings that aid in refining future lifestyle intervention approaches for high-risk Black and Latina people and facilitate their scalability in community-based settings, ultimately improving maternal and infant long-term health and promoting health equity.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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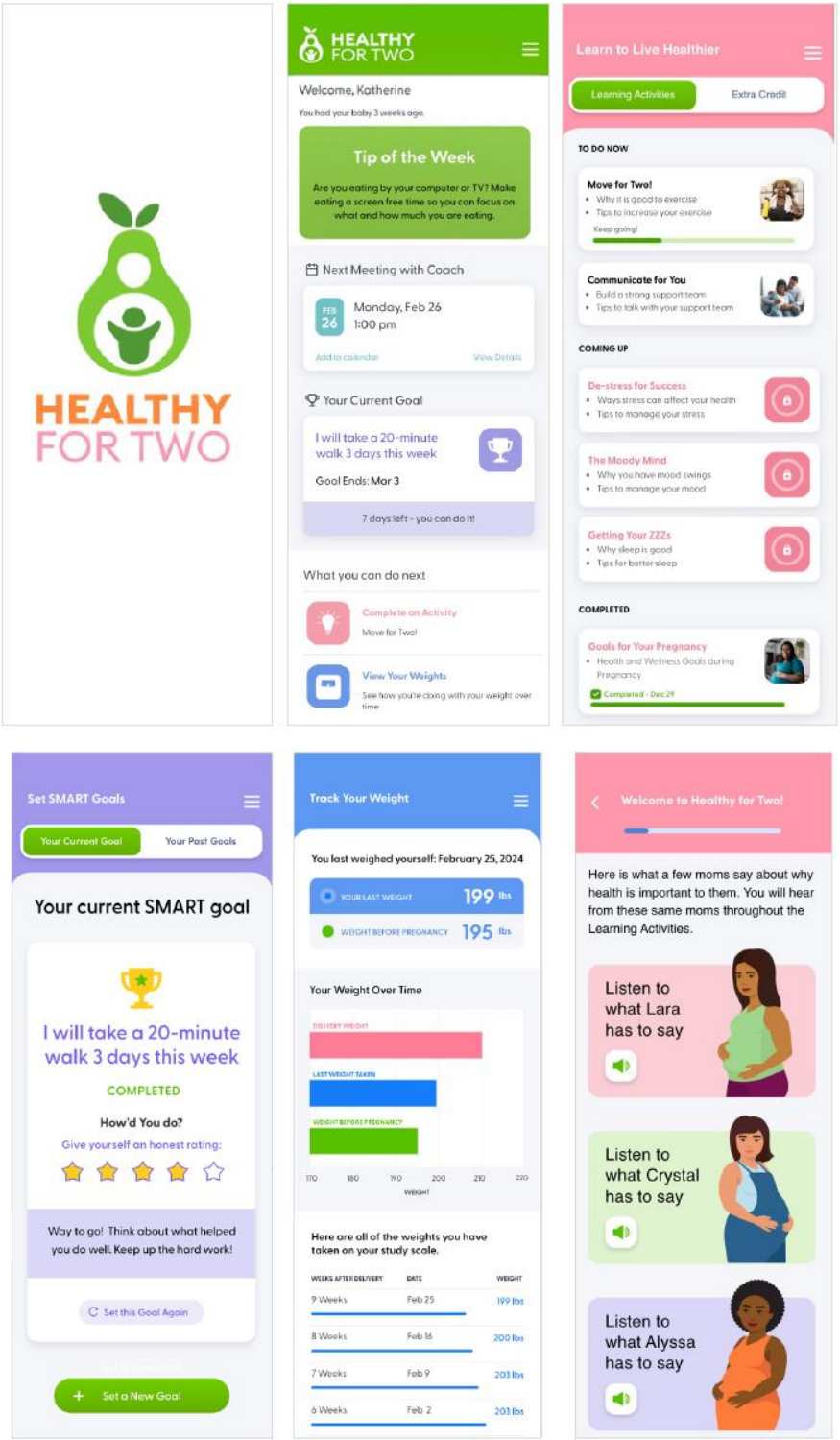
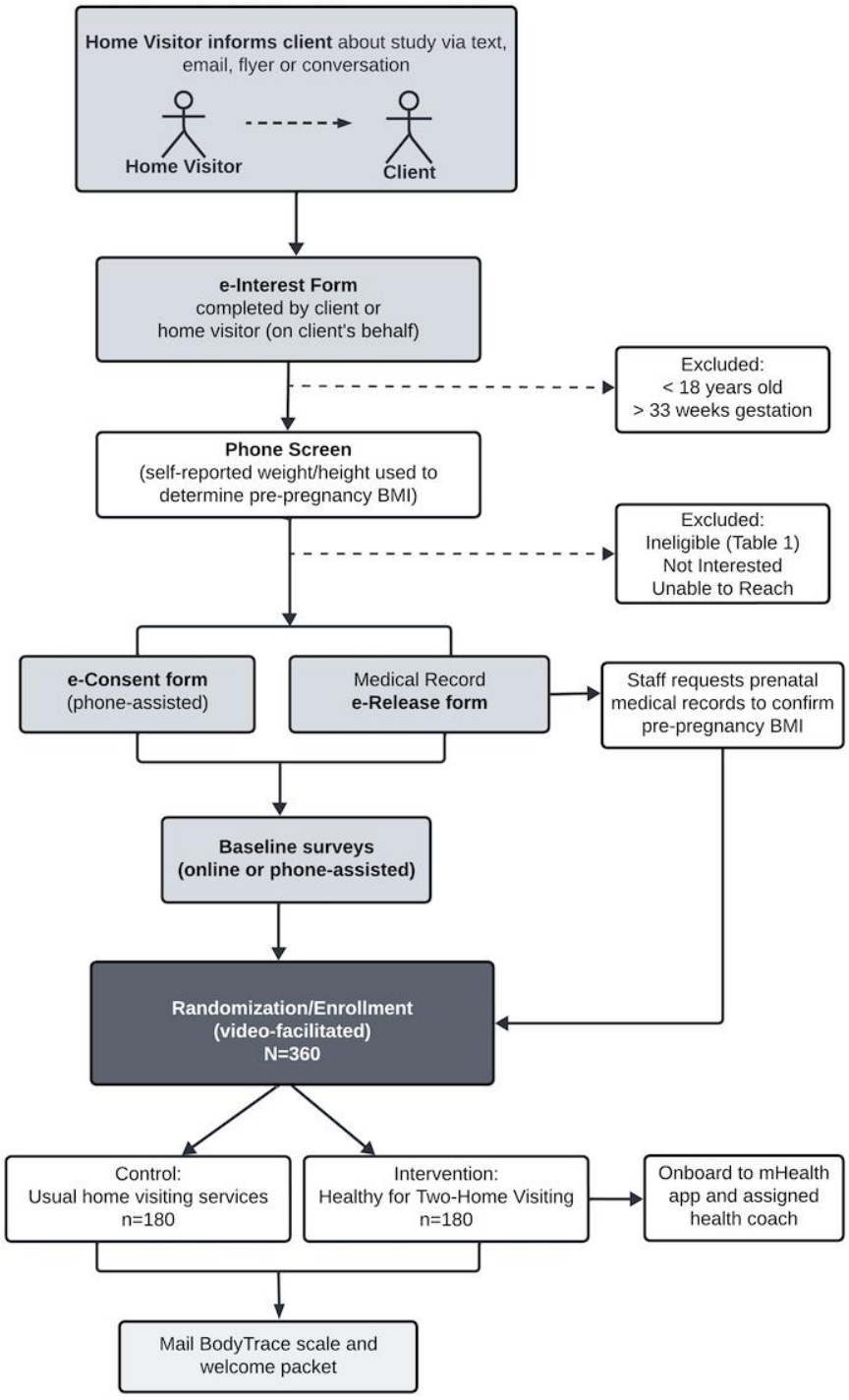
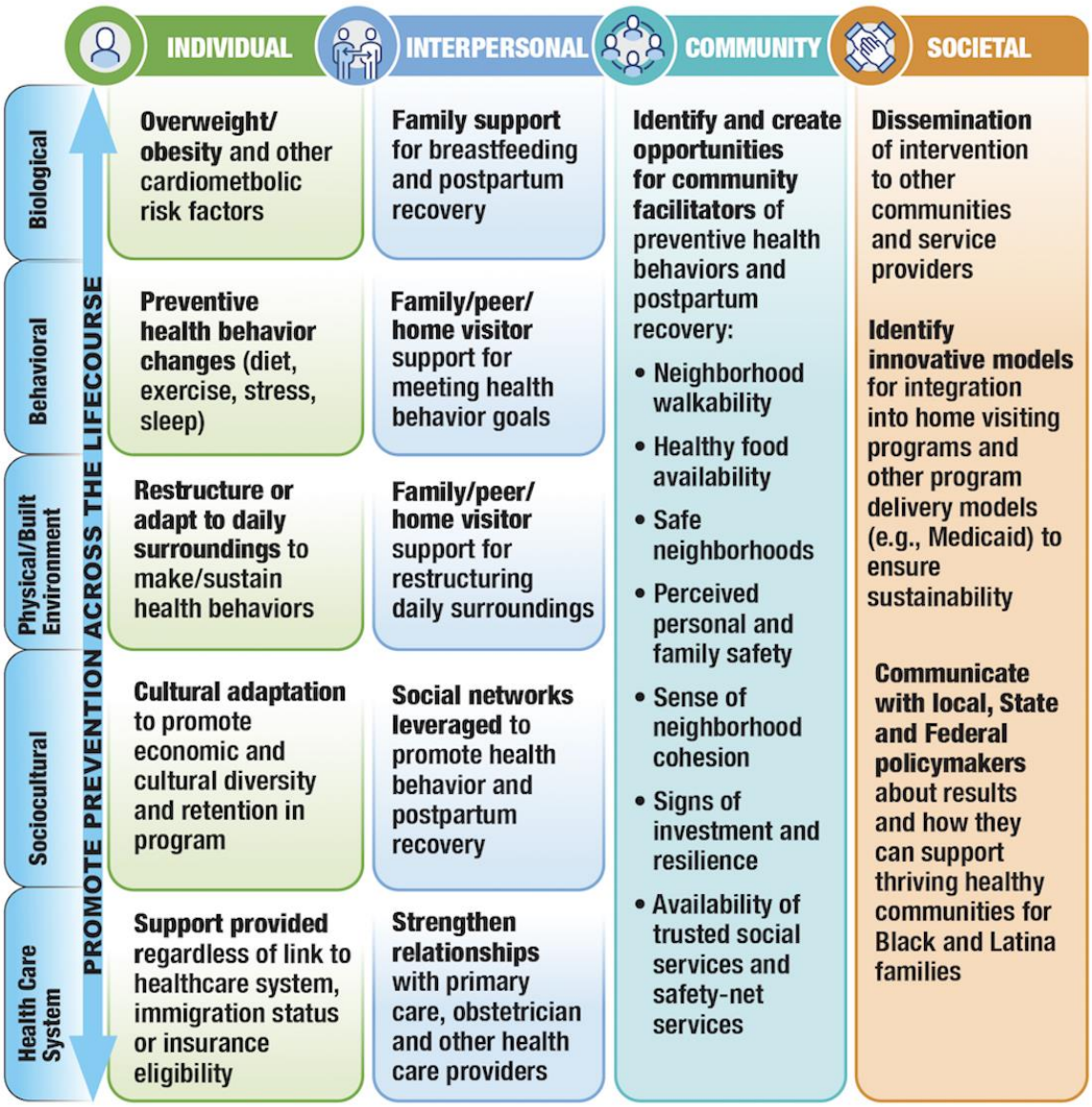
Supplementary Files

Figures


HEALTHY FOR TWO
HEALTHY FOR TWO
Welcome, Katherine
You had your baby 3 weeks ago.
Tip of the Week
Are you eating by your computer or TV? Make eating a screen free time so you can focus on what and how much you are eating.
Next Meeting with Coach
Monday, Feb 26
1:00 pm
Add to calendar
View Details
Your Current Goal
I will take a 20-minute walk 3 days this week
Goal Ends: Mar 3
7 days left - you can do it!
What you can do next
Complete an Activity
Move for Two!
View Your Weights
See how you're doing with your weight over time
Learn to Live Healthier
Learning Activities
Extra Credit
TO DO NOW
Move for Two!
Why it is good to exercise
Tips to increase your exercise
Keep going!
Communicate for You
Build a strong support team
Tips to talk with your support team
COMING UP
De-stress for Success
Ways stress can affect your health
Tips to manage your stress
The Moody Mind
Why you have mood swings
Tips to manage your mood
Getting Your ZZZs
Why sleep is good
Tips for better sleep
COMPLETED
Goals for Your Pregnancy
Health and Wellness Goals during Pregnancy
Completed - Dec 29
Set SMART Goals
Your Current Goal
Your Past Goals
Your current SMART goal
I will take a 20-minute walk 3 days this week
COMPLETED
How'd You do?
Give yourself an honest rating:
Way to go! Think about what helped you do well. Keep up the hard work!
Set this Goal Again
Set a New Goal
Track Your Weight
You last weighed yourself: February 25, 2024
YOUR LAST WEIGHT 199 lbs
WEIGHT BEFORE PREGNANCY 195 lbs
Your Weight Over Time
DELIVERY WEIGHT
LAST WEIGHT TAKEN
WEIGHT BEFORE PREGNANCY
170 180 190 200 210 220
WEIGHT
Here are all of the weights you have taken on your study scale.
WEEKS AFTER DELIVERY DATE WEIGHT
9 Weeks Feb 25 199 lbs
8 Weeks Feb 16 200 lbs
7 Weeks Feb 9 203 lbs
6 Weeks Feb 2 203 lbs
Welcome to Healthy for Two!
Here is what a few moms say about why health is important to them. You will hear from these same moms throughout the Learning Activities.
Listen to what Lara has to say
Listen to what Crystal has to say
Listen to what Alyssa has to say


Home Visitor informs client about study via text, email, flyer or conversation
Home Visitor
Client
e-Interest Form
completed by client or
home visitor (on client's behalf)
Excluded:
< 18 years old
> 33 weeks gestation
Phone Screen
(self-reported weight/height used to
determine pre-pregnancy BMI)
Excluded:
Ineligible (Table 1)
Not Interested
Unable to Reach
e-Consent form
(phone-assisted)
Medical Record
e-Release form
Staff requests prenatal
medical records to confirm
pre-pregnancy BMI
Baseline surveys
(online or phone-assisted)
Randomization/Enrollment
(video-facilitated)
N=360
Control:
Usual home visiting services
n=180
Intervention:
Healthy for Two-Home Visiting
n=180
Onboard to mHealth
app and assigned
health coach
Mail BodyTrace scale and
welcome packet


INDIVIDUAL
INTERPERSONAL
COMMUNITY
Ssocietal
PROMOTE PREVENTION ACROSS THE LIFECOURSE
Biological
Behavioral
Physical/Built Environment
Sociocultural
Health Care System
Overweight/ obesity and other cardiometbolic risk factors
Family support for breastfeeding and postpartum recovery
Identify and create opportunities for community facilitators of preventive health behaviors and postpartum recovery:
• Neighborhood walkability
• Healthy food availability
• Safe neighborhoods
• Perceived personal and family safety
• Sense of neighborhood cohesion
• Signs of investment and resilience
• Availability of trusted social services and safety-net services
Dissemination of intervention to other communities and service providers
Identify innovative models for integration into home visiting programs and other program delivery models (e.g., Medicaid) to ensure sustainability
Communicate with local, State and Federal policymakers about results and how they can support thriving healthy communities for Black and Latina families
Preventive health behavior changes (diet, exercise, stress, sleep)
Family/peer/ home visitor support for meeting health behavior goals
Restructure or adapt to daily surroundings to make/sustain health behaviors
Family/peer/ home visitor support for restructuring daily surroundings
Cultural adaptation to promote economic and cultural diversity and retention in program
Social networks leveraged to promote health behavior and postpartum recovery
Support provided regardless of link to healthcare system, immigration status or insurance eligibility
Strengthen relationships with primary care, obstetrician and other health care providers