Testing the effectiveness of the *Her Health* Program to add healthcare value in the fourth trimester

Sponsor: The Donaghue Foundation

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Summary of Changes from Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale

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BACKGROUND

Patient navigation in healthcare settings is a critical strategy for promoting health equity. Patient navigation increases access to screening, shortens time to diagnostic resolution, and improves outcomes in the oncology field, particularly in health-disparate populations, such as persons of color or rural populations. Successes in cancer care at reducing health disparities allude to potential for patient navigation to reduce health disparities in perinatal populations. Indeed, emerging work supports the potential for postpartum patient navigation to improve access to early postpartum care, and qualitative work among obstetrical and primary care providers demonstrates that both disciplines believe that supplementing postpartum healthcare with patient navigation holds promise for improving access to care and outcomes and reducing health disparities.

Importantly, there is growing evidence that experiences of perceived discrimination and microaggressions in perinatal healthcare increase the risk of adverse perinatal outcomes, nonattendance to visits, and poorer quality of healthcare interactions. Patient navigation and education are both proven strategies for increasing trust in healthcare and improving patient self-efficacy. In response to this evidence, we have designed the Her Health patient navigation program integrated with historically informed, culturally competent education to improve self-efficacy, self-advocacy, and medical trust. This evidence-based program builds on preexisting work in cancer patient navigation, and emerging work in perinatal patient navigation, and will be finalized as part of this project through a community-engaged research design to best address the needs of our community

STUDY AIMS & HYPOTHESES

1. Determine the effectiveness of Her Health to increase access to postpartum healthcare among a diverse sample of Medicaid-enrolled postpartum persons.
    a. Hypothesis 1a: The proportion of persons who attend the comprehensive, postpartum visit will be greater in the Her Health group compared to the Standard Care group.
    b. Hypothesis 1b: Her Health participants will have a greater number of primary care and outpatient visits in the first 12 months postpartum compared to Standard Care participants.
2. Determine the effectiveness of Her Health to increase medical trust, self-efficacy, and health literacy among a diverse sample of Medicaid-enrolled postpartum persons.
    a. Hypothesis 2a: Her Health participants will have a greater increase in medical trust compared to Standard Care participants between baseline and 12 months postpartum as measured by the Group-Based Medical Mistrust Scale.
    b. Hypothesis 2b: Her Health participants will have a greater increase in health literacy compared to Standard Care participants between baseline and 12 months postpartum as measured by the Rapid Estimate of Adult Literacy in Medicine (REALM).
    c. Hypothesis: Her Health participants will have a greater increase in self-efficacy compared to Standard Care participants between baseline and 12 months postpartum as measured by the PROMIS General Self-Efficacy measure.
3. Compare total healthcare spending during the first postpartum year between Her Health and Standard Care participants. This aim will be accomplished with the dataset constructed for Aim 1. Total healthcare spending is defined as the sum of insurer-paid amounts.
    a. Hypothesis 3: Her Health participants will have lower total healthcare spending compared to the Standard Care participants over the first postpartum year.

STUDY DESIGN

Overview

We will conduct a randomized controlled trial with an adaptive group sequential design assessing access to healthcare (primary outcome) for up to 500 newly postpartum persons with Medicaid-paid births. Participants will be randomized within one week of delivery in a 2:1 design to the intervention (called Her Health) or to Standard Care respectively. Her Health is a patient navigation intervention led by community health workers over the first 12 months after delivery. Healthcare access data will be linked across the partnering organization's electronic medical record and the Louisiana Department of Health Medicaid Database and Vital Records Database. Medical trust and self-efficacy will be assessed via survey at baseline (i.e., within 7 days postpartum) and with an end-of-study survey to be disseminated after 12 months of intervention or standard care. Total healthcare costs across the first postpartum year will be compared between intervention and control groups also using medical claims data. Sociodemographic, social determinants of health and general and obstetrical medical history covariates will be collected via interview at enrollment.

Duration of study

The study will enroll patients beginning in 2024. We anticipate enrollment to last about 12 months. The data abstraction, analysis, and publication are anticipated to be completed in 2026.

Setting and Participating Organizations

Recruitment, enrollment, and data collection will be led by the Woman's Hospital Research Department, directed by Dr. Sutton.

STUDY ENROLLMENT

Number of participants

Up to 500 newly postpartum persons will be enrolled.

Eligibility Criteria

Inclusion criteria:

- At least 16 years old at the time of consent.
- Gave birth within 7 days before randomization
- Medicaid enrolled
- Address of residence within a disadvantaged area (ADI>5).
- Clearly understands the study procedures and visit schedule, alternative treatments, and risks involved with the study, and voluntarily agrees to participate by giving verbal and written informed consent

Exclusion criteria*:*

- Use of private health insurance exclusively
- Does not speak English.
- Plans to move out of state during the study time period
- Unwilling to provide permission to link study records, medical records, and Medicaid and Vital Records Database records.
- Unwilling to provide informed consent
- Unwilling to be randomized.

Recruitment Strategies

We will enroll patients via direct recruitment during their delivery hospital stay in the Mother/Baby unit. Participants will be identified preliminarily by medical record review for age, delivery date, residential address, language spoken, and health insurance. If potentially eligible, the minimal information necessary will be recorded, and the patient approached by the study team to learn about the study. Should a patient choose to enroll, eligibility will be determined, informed consent will be obtained, baseline data will be collected, and then randomization will occur. For patient's convenience, they will be presented with the option to spread these enrollment steps out (i.e. approach, consenting, data collection, randomization), as this process can take up to 30-40 minutes. It is also necessary to ensure they receive ample time to review the consent and understand the study requirements.

Additional strategies may be deployed as well should an earlier introduction be deemed feasible and amenable. A public interest form will be available for an individual to complete independently to express interest. Advertisements may also be posted on hospital campus, including Mother/Baby unit rooms, prompting patients to ask their nurse about the study who can then call a coordinator or scan a QR code to learn more. Direct contact (calls, approach at appointments, messaging through text or MyChart) may also be deployed to introduce the study to potential participants in pregnancy. The study team will monitor the interest form and study cellphone to return inquiries in a timely manner.

Partial Waiver- HIPAA Authorization

A partial HIPAA authorization waiver granted by the reviewing institution's IRB will allow for direct recruitment strategies and participant contact for which personal information is required to identify preliminary eligibility.

Participant Withdrawal/Lost-to-follow-up

Participants may withdraw voluntarily from the study at any time upon request or the investigator may terminate a subject's participation at any time during the study. Reasons for Withdrawal:

- Ineligible per inclusion/exclusion criteria: If a participant has consented to participate in the study but is determined ineligible per the inclusion/exclusion criteria, the participant will be withdrawn from the study.
- Protocol non-compliance: If a participant cannot comply with all study-required procedures (e.g., data collection), the participant may be withdrawn from the study.
- Participant withdrawal of consent: Participation in this study is voluntary and participants may decide not to participate or may leave the study at any time. Information that has already been collected may still be used, but no new information will be collected.
- Investigator decision: The site investigator may decide to withdraw a participant at any time if it is in the best interest of the participant to be withdrawn (e.g., for health and safety reasons).
- Study or clinical site terminated by sponsor: The sponsor may decide to terminate the study or a clinical site. Therefore, participants enrolled in the study and/or at the study site will be withdrawn.

STUDY SCHEDULE AND PROCEDURES

Study Schedule

Participants who choose to participate will complete one, in-person study visit within 7 days after giving birth. Depending on the randomization assignment, two-thirds of participants will also receive Her Health Navigation. Participants will then participate in another study visit that will be 52-56 months postpartum and will take place in person, over the phone, or electronically. This visit will consist of

updating contact information and follow-up surveys. Medical record abstraction will be completed relevant to the participant's pregnancy and postpartum health as well as the health of her offspring. See **Table 1** for the study schedule and procedures at each time point.

Visit 1: Within 7 Days Postpartum

Location: In-person at Woman's Hospital

Length: 30-40 minutes

- **Screening:** Pregnant persons who recently delivered at Woman's Hospital will be identified by medical record review. For those preliminarily eligible, the study and eligibility criteria will be reviewed with them (See Recruitment Strategies Section). It will be emphasized that participation in this study is optional and does not impact the healthcare delivery for individuals who choose to participate.
- **Informed consent**: Following preliminary eligibility screening, the participant will be presented with an informed consent form to review and sign (may be paper or digital). A participant may opt out of the study and decline should she choose. After obtaining consent, participants will be provided with a copy of the consent form (either paper or digital) and proceed to be enrolled in the study.
- **Surveys:** Surveys may be administered electronically, in person, via phone interview, or on paper. The following information will be collected at this visit:
    - Contact information: Participant name(s), date of birth, phone number, mailing address, email address, and communication preference will be collected and stored in REDCap*
    - Demographics*
    - Group-Based Medical Mistrust Scale*
    - Rapid Estimate of Adult Literacy in Medicine (REALM)*
    - PROMIS General Self-Efficacy Mistrust Scale*
    - General and obstetrical history
    - Adverse Childhood Experiences Score
    - Experience in Discrimination Scale
    - Everyday Discrimination Scale
    - Ross Neighborhood Disorder Scale
    - Psychological General Well-Being Index
    - Social determinants of health (will be abstracted from medical record)
    - All Aspects of Health Literacy (AAHLS)

    *Must be completed prior to randomization. The others may be completed within the first 30 days of study enrollment to reduce the burden.
- **Randomization:** After completion of baseline surveys, participants will be randomized to either intervention (Her Health navigation) or control (Standard Care).

Table 1. Research procedures

	Visit 1: ≤7 days postpartum	**Visit 2: 52-56 weeks postpartum**
Informed Consent	X	
Demographics	X	
Randomization	X	
Contact information	X	X
Demographic information	X	
Group-Based Medical Mistrust Scale	X	X
Rapid Estimate of Adult Literacy in Medicine (REALM)	X	X
PROMIS General Self-Efficacy Mistrust Scale	X	X
Adverse Childhood Experiences	X	
Experience in Discrimination Scale	X	X
Everyday Discrimination Scale	X	X
Ross Neighborhood Disorder Scale	X	X
Social Determinants of Health Screening		X
Psychological General Well-Being Index	X	X
Medical record abstraction	X	X
Compensation ($60)	X	
Compensation ($75)		X

- **Compensation:** A $60 gift card will be provided to the participant
- **Primary physician notification:** Should a participant qualify and desire to enroll, if she permits, her primary care physician (OB/GYN, PCP, or designee by participant) will be notified by the study team of the participant's participation in this study.

Visit 2: 12 months postpartum

Location: In-person, over the phone, or independently

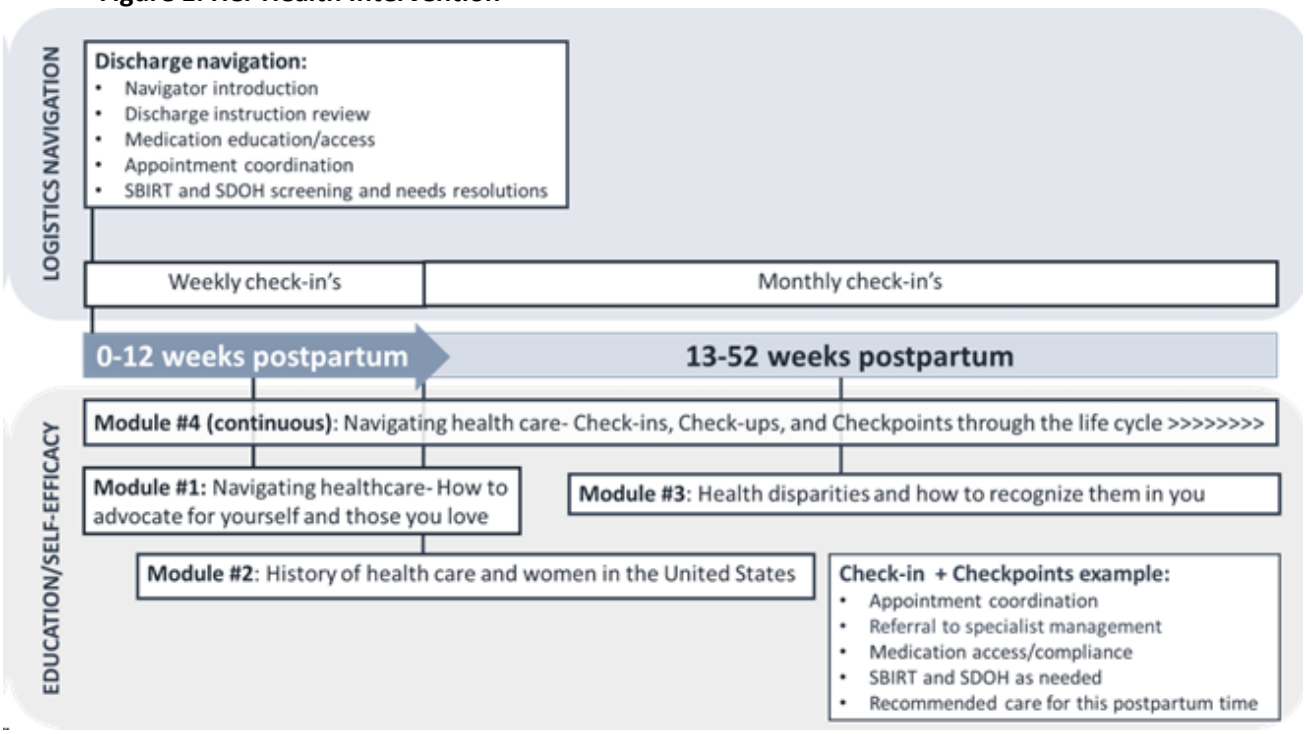
Length: 30 minutes

- **Surveys:** Surveys may be administered electronically, via in-person or phone interviews, or paper questionnaires. The following information will be collected at this visit:
    - Contact information: previously collected contact information will be confirmed and updated as necessary.
    - Group-Based Medical Mistrust Scale
    - Rapid Estimate of Adult Literacy in Medicine (REALM)
    - PROMIS General Self-Efficacy Mistrust Scale
    - General health history
    - Social determinants of health
    - General and obstetrical history
    - Experience in Discrimination Scale
    - Everyday Discrimination Scale
    - Ross Neighborhood Disorder Scale
    - Psychological General Well-Being Index
    - All Aspects of Health Literacy Scale (AAHLS)
- **Compensation:** A $75 gift card will be mailed, texted, or emailed to the participant (based on their preference)

Intervention to be tested: ***Her Health***

Her Health is a patient navigation intervention delivered by community health workers across the first postpartum year (**Figure 1**). Her Health has two interspersed components: Navigation and Education. Her Health Navigation is delivered through weekly and monthly check-ins between participant and navigator. Her Health navigators will deliver historically informed and culturally competent education designed to promote self-efficacy and self-advocacy within the healthcare system. There are 4 modules: 3 one-on-one sessions (about 6 weeks, 3 months, and 6 months postpartum) and 1 continuous module interspersed during weekly/monthly check-ins across the intervention. The Her Health education component is an evidence-based and culturally informed curriculum delivered by the navigator in one-on-one (n=4) designed to teach self-efficacy and self-advocacy within the healthcare system to improve medical trust. The module topics will be on a schedule relevant to postpartum timing. Her Health education will be developed with direction from a Community Advisory Board; therefore, the implementation and content of the navigation and education components is subject to change and can be customized based on needs of participants but will be carefully documented.

Figure 1. Her Health Intervention



Assessment of Safety

Specification of Safety Parameters

Safety monitoring for this study will focus on unanticipated problems involving risks to participants, including unanticipated problems that meet the definition of a serious adverse event.

Unanticipated Problems

This study considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets all the following criteria:

- **Unexpected** in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied.
- **Related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

Participation in this study does involve potential risks of a breach of confidentiality of the medical record and associated privacy of the participants. Such risks will be minimized by 1) removing participant identifiers from clinical data forms/data extracts outside of REDCap; 2) limiting access to linking codes assigned to the information with direct participant identifiers. Only the Woman's Hospital Director of Scientific Research or her designees will have access to this information, minimizing the likelihood of a breach of confidentiality.

Serious Adverse Events (SAE)

Any SAE, regardless of cause, occurring after the participant is enrolled must be reported to the Principal Investigator or designee as soon as possible after knowledge of the event so that it can be reported to the IRB within the required timeframe.

A Serious Adverse Event (SAE) is any adverse experience that results in any of the following outcomes:

- Death
- A life-threatening experience
- Inpatient hospitalization or prolongation of existing hospitalization (excluding routine obstetric hospitalizations)
- A persistent or significant disability/incapacity
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Participants enrolled in this study have a minimal to extremely low risk of experiencing an SAE, as the study will not administer any medication or conduct any health care intervention of any kind as part of this project.

Adverse Events (AE)

An Adverse Event (AE) is any untoward or unfavorable medical occurrence, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptoms, or disease. Adverse events can encompass both physical and psychological harm. These events will be collected and documented in the participant chart and the Woman's REDCap system. Adverse events reporting to the IRB will follow the Woman's Hospital Foundation IRB policy.

Reporting Procedures

Incidents or events that meet the protocol's criteria for **unanticipated problems** require the creation and completion of an unanticipated problem report form. The following information will be included when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

- Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number.
- A detailed description of the adverse event, incident, experience, or outcome.
- An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem.
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

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

- Unanticipated problems that are serious adverse events will be reported to the IRB and the study coordinator within 2 business days of becoming aware of the event.
- Any other unanticipated problem will be reported within 2 weeks of the investigator becoming aware of the problem.

DATA MANAGEMENT

Data collection and storage

Study data will be maintained in hard copy in patient charts and as well as a REDCap database. All charts will be always locked in a secure area with restricted access when not in use. Physical charts will be kept for at least 3 years after study closure. Access to the REDCap database is exclusive and only investigators and study personnel will be granted access.

To ensure data is as meaningful and robust as possible, a minimum uniform standard of care must be defined. The following data (Medical Record Number, Name, Dates (informed consent, DOB, hospital admission/discharge dates, etc.), Demographics, Medical history (signs, symptoms, diagnosis, treatment), and Medications are expected to be collected for all participants. Although some data may be reviewed from the patient before the consent as part of pre-screening, no data should be included in the database until after consent is obtained from the participant. Medical record release forms and survey data can be collected at the time of enrollment or may be done at a follow-up visit.

Medical record abstractions

When available (i.e. medical records accessible or provided upon request from OBGYN providers, LDH, Woman's Hospital, etc.), a retrospective chart review will be completed to have an in-depth characterization of the participants' general and obstetrical history. Manually abstracted data will be saved in REDCap. Variables to be extracted include, but are not limited to:
Maternal:

- Demographic variables: mother's hospital ID, baby's hospital ID, mother's date of birth, race, height, weight, body mass index (BMI), marital status, insurance type, education level, language spoken, employment status, maternal residential address, sexual orientation
- Obstetric history and general health history: smoking status, smoking history, parity, chronic hypertension, diabetes, previous c-section, history of preterm birth, breastfeeding history, alcohol and/or illicit drug use, laboratory results, and hospitalizations
- Obstetric variables: singleton versus multiple gestation, estimated gestational age at delivery, delivery date, route of delivery, length of hospital stay, induction of labor (yes/no) and reason (elective versus medical), diabetes diagnosis, hypertensive disorder of pregnancy diagnosis, gestational diabetes, gestational weight gain, severe maternal morbidity, maternal death.
- Infant variables: Sex, birth weight, birth length, date of birth, NICU admission (yes/no), length of stay, 1- and 5-minute APGAR scores

Confidentiality

Research data will be kept on Woman's firewall-protected server(s). Research data will be entered and managed using the secure web application Research Electronic Data Capture (REDCap). REDCap is protected by a login as well as encryption. Paper records will be maintained in a locked cabinet in a locked room by the study coordinator at the study site (Woman's Hospital Research) when not in use.

All study participants will be assigned a de-identified study ID. A key with each participant's de-identified ID, name, and medical record number will be maintained securely in REDCap. Research personnel will access the minimum amount of data required to carry out their study-related duties.

Sharing of Results with Participants

Individual results will not be shared with participants. Compiled, de-identified results will be shared in abstracts, presentations, and manuscript publications.

Data Usage

We intend to submit the results of this study for publication.

Data Analysis Plan

We will use a one-sided two-sample test of proportions to make interim and final decisions on whether the intervention is effective in increasing postpartum visit attendance (Aim 1). After n=150 primary outcomes are available, we would stop the control arm (i.e., Standard Care) and only enroll patients in the intervention arm (i.e., Her Health program) if the p-value of the one-sided two-sample tests of proportions is less than 0.03. We will do the same thing at n=300 participants and use this critical limit to make a final decision on whether the intervention is superior to standard care if we reach the maximum sample size.

Survey differences (baseline, post, and differences) by intervention group will be assessed using Wilcoxon rank-sum tests (Aim 2). Wilcoxon rank-sum tests will also be used to test whether healthcare spending over the first year differed by intervention group (Aim 3). Secondary binary outcomes will be assessed using two-sample tests of proportions or Fisher exact tests when expected counts are low. Fisher exact tests will be used for categorical variables with more than two levels. If necessary due to unexpected confounding, multivariable linear regression will be used for continuous outcomes and multivariable logistic regression will be used for binary outcomes (with appropriate extensions for multi-category outcomes to ordinal or multinomial regression). Randomization schedules and interim and final statistical analyses will be carried out by the study biostatistician.

Stopping Rules with Interim Analysis

Stopping decisions will be made after 150, 300, and 450 participant outcomes are obtained if the p-value for a one-sided two-sample test of proportions is below a cutoff level (i.e., 0.03). This p-value was determined via simulation to ensure that the type I error assuming a postpartum visit attendance rate of 50% in both groups was under 0.05 (note, that the local baseline rate of postpartum visit attendance is 50%). Assuming the intervention increases the postpartum visit attendance rate by 15%, which is like the study by Yee et al. (1), the simulated power was 88.3% for the adaptive group sequential design approach described above, and the average number of patients enrolled in the intervention was n=355. This includes the patients randomized to the intervention and the number of patients who would be given the intervention if the trial stopped early.

ETHICS/PROTECTION OF HUMAN PARTICIPANTS

Ethical Standard

The principal investigator will ensure that this study is conducted in full conformity with the principles outlined in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Woman's Hospital Foundation IRB for review and approval. The Principal Investigator and all research staff are trained in and must agree to abide by all laws, rules, and regulations governing the collection, handling, and processing of protected health information (PHI), including without

limitation the Health Insurance Portability and Accountability Act (HIPAA), as well as conditions, rules, and regulations of any Institutional Review Board(s) involved in the study.

Throughout the study, any amendment or modification to this protocol or related consent forms will be sent to the IRB for review and approval before changes are implemented. As with the original protocol review, copies of approval letters for subsequent protocol and/or consent form modifications will be linked to the protocol/consent version number and retained by Woman's Hospital.

Informed Consent Process

Woman's Hospital policy on obtaining, recording, and maintaining Informed Consent and HIPAA authorization will be followed. Informed consent is a process that is initiated before the person agrees to participate in the study and continues throughout the person's study participation. The informed consent process will be conducted and documented in the source document (including the date), and the form signed before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their or their infant's medical care will not be adversely affected if they decline to participate in this study.

The birthing person's informed consent form will be Institutional Review Board (IRB)-approved, and the participant will be asked to read and review the document. The research staff will explain the research study to the participants and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and their rights as research participants. Participants will have the opportunity to carefully review the consent form and ask questions before signing. The participants will be allowed the opportunity to discuss the study with their family or surrogates or think about it before agreeing to participate. The participant will sign the informed consent document before any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be provided to the participants for their records.

JUSTIFICATION OF SPECIAL POPULATIONS

There are no study funds available to translate materials into Spanish, therefore only English speakers will be included.

RISK/BENEFIT TO STUDY PARTICIPANTS

Risks

Participants are exposed to no more than minimal risks during study participation. A potential risk in questionnaire administration involves the socio-psychological risk for the individual resulting from inadvertent disclosure of confidential medical history information. This potential risk is guarded against by storage of completed questionnaires in a locked filing system and on a restricted database platform (REDCap) and by labeling other phenotypic data using ID numbers only.

Some questions in questionnaires may make participants uncomfortable. To reduce the risk of discomfort during the follow-up questionnaires, the questionnaire will emphasize the voluntary nature of participating in the survey and that the participant can choose to not answer any given question if they do not want to.

Benefits

Those who are randomized to the Her Health program will receive the benefit of the Her Health intervention delivered by a community health worker across the first postpartum year. For those randomized to the Standard Care group, there will be no direct benefits.

COMPENSATION

Each participant will receive compensation for their participation in the study. Compensation will be in the form of gift cards. After Visit 1, the study personnel will issue to the participant a $60 gift card. The participant will have the option of the card being mailed or sent via text or email. A $75 gift card will be mailed, texted, or emailed to the participant at the end of the study visit which will take place 52-56 weeks postpartum. Accordingly, the participant could receive a total of $135 in compensation over the study duration. If the participant withdraws early from the study, they will keep the compensation that they have received for the study procedures completed to date. Compensation will only be dispensed to participants after they have completed study procedures for that time point.

ALTERNATIVES

Agreeing to participate in this research will not change the normal medical care that the participants and their infants will receive. Participants may decide to participate in this research or not participate in this research, but this will change nothing about the medical care that is provided.

SPONSOR

The study is funded by the Donaghue Foundation.

REFERENCES

1. Yee, L. M. *et al.* Using a patient navigator to improve postpartum care in an Urban Women's Health Clinic. *Obstet. Gynecol.* **129**, 925–933 (2017)