INVESTIGATOR STUDY PLAN – Moms@Home
V1.0

Official Study Title: Development of a Mobile Health Intervention to Improve Blood Pressure Management in Pregnancy (Moms@Home)

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1. TITLE
Development of a Mobile Health Intervention to Improve Blood Pressure Management in Pregnancy (Moms@Home)

2. EXTERNAL IRB REVIEW HISTORY
NA

3. PRIOR APPROVALS:
NA

4. OBJECTIVES
Aim 1: Conduct a pilot randomized controlled trial (RCT) of Moms@Home vs. enhanced standard care (ESC). We will enroll 100 pregnant women (50% from racial/ethnic minority groups) with gestational or chronic HTN to determine whether Moms@Home vs. enhanced standard care (BP monitor, diary) improves HBPM adherence (primary outcome). We will also determine the feasibility, acceptability, and sustainability of the 8-week intervention. Hypothesis 1: Participants in the intervention MOMS@HOME group will have better adherence to HBPM, compared to participants in the control ESC group at 8 weeks.

5. BACKGROUND
Description of the Problem : Hypertension in pregnancy is highly prevalent, its frequency is increasing in the United States, and accounts for 40% of maternal mortalities in the US. The time required for frequent in-person visits, inadequate counseling, and the asymptomatic nature of hypertension are major barriers to effective blood pressure (BP) control in pregnant women. These issues can be addressed through the use of home BP monitoring (HBPM), which reduces the risk of preventable and devastating clinical events and reduces racial inequities in people who are pregnant. Obstetric societies recommend HBPM for all people who are pregnant with hypertension, but many studies suggest that the rates of counseling for HBPM and uptake are low.

Significance : Barriers to blood pressure (BP) control in people who are pregnant can be addressed by home BP monitoring (HBPM), which has multiple advantages over clinic-based BP but is underutilized in people who are pregnant. Improving BP control and reducing health inequities are top national priorities, as the adverse effects of hypertensive disorders in pregnancy are lifelong and convey a 2–8-fold increased risk of cardiovascular disease.[1–3]
Although people wo are pregnant are motivated to self-manage BP, barriers to BP control based on clinic-based BP measures include the challenges with mothers having time off from work and costs for frequent visits, lack of information about self-care, and low engagement with in-person clinic visits.[4-9] Clinic-based BP is a poor surrogate for average daily BP, and HBPM values are superior with regard to reliability and prognostic value for mortality and adverse pregnancy events.[10–13] By facilitating more timely HTN diagnosis and BP control, HBPM reduces the risk of preventable and devastating clinical events.[14–17] Adults using HBPM are more likely to take BP medications and have diagnosed, treated, and controlled HTN.[18–20]
Digital health interventions can overcome barriers to HTN management but need to be tested in people who are pregnantwith HTN. CareEvolution's MyDataHelps™ (MDH) mobile health application (app) was designed to promote HBPM and facilitate communication between people

and their care teams. Designed by diverse Patient Advisory Groups, MDH's secure health dashboard displays BP data and sends text notification reminders to perform HBPM. The MDH app has been used to support multiple NIH-funded cohorts including the electronic Framingham Heart Study (eFHS), RURAL, MIPACT, and DETECT.[21] In the eFHS, women were more likely than men to enroll in HBPM, with 62% regularly using HBPM through 1 year.[21,22] In pregnant women, digital health interventions improve patient engagement and health equity while allowing for early detection of pregnancy-related problems and communication with care teams.[17,23] Digital health also reduces wait times and access barriers based on geography or mobility.[24-28] Increasing smartphone adoption and validated Bluetooth BP monitors, with ability to transmit data remotely, have made HBPM more accessible.[29-31]
The most effective self-management interventions, including digital health interventions in pregnancy, are grounded in Social Cognitive Theory and incorporate four primary constructs: training/modeling, self-monitoring, goal setting, and reinforcement.[32,33] Moms@Home will integrate these constructs to increase self-efficacy and improve BP control.[34,35]
Storytelling is an evidence-based approach with universal appeal to support behavior change and BP control, especially in racial/ethnic minority groups. Storytelling is based on a rich oral tradition common in Black and Hispanic cultures and appeals to the human affinity for sharing stories.[36,37] This approach is especially effective at reaching persons of racial/ethnic minority groups if the stories are grounded in shared experiences.[38,39] Storytelling's effectiveness in changing behavior relates to breaking down cognitive resistance through transportation (absorption in the story) and "homophily" (similarities between the storytellers and participants) to change attitudes, skills, and behaviors[37,40]. Integration with technology and the care team can sustain behavior change, but input from patients and providers is critical.

6. INCLUSION AND EXCLUSION CRITERIA*

Participant inclusion/exclusion:

Inclusion criteria:

(1) Age 18-50
(2) Singleton or multiple pregnancies
(3) English or Spanish speaking
(4) Diagnosis of Chronic hypertension (8-26 weeks gestational age) or gestational hypertension (20-26 weeks gestational age)
(5) A patient of the UMass Memorial Health OB/MFM clinics in Worcester, MA
(6) Willing to share HBPM data
(7) Comfortable with the use of smartphones and mobile apps

Exclusion criteria:

(1) Severe HTN (BP greater than or equal to 160/110mmHg at the enrollment visit)
(2) Current diagnosis of preeclampsia
(3) Active substance use
(4) Serious physical illness or any illness that makes them unable to interact with a smart device
(5) Enrolled in another HBPM program
(6) Excluded from study participation by their provider
(7) Inability to provide informed consent

(8) Prisoners

OB/MFM Provider Inclusion/Exclusion (N=10):

Inclusion criteria: OB/MFM providers (attending physicians, residents, advanced practitioners, nurses) involved in caring for RCT participants.
Exclusion criteria: Inability to verbally communicate in English.

7. STUDY-WIDE NUMBER OF SUBJECTS

NA

8. STUDY-WIDE RECRUITMENT METHODS

NA – this is not a multi-site study.

9. STUDY TIMELINES

Duration of an individual subject's participation in the study: 8 weeks
Duration of the post-study focus groups is estimated to be 1-1.5 hours
Duration anticipated to enroll all study subjects: 1.5 years, longer if not meeting recruitment goals.
Estimated timeline for investigators to complete this study: 2 years

10. STUDY ENDPOINTS

Aim 1:

Primary outcome measures:

- Home Blood Pressure Monitoring (HBPM) adherence at 8 weeks
- Feasibility of Moms@Home– assessed through post-intervention focus groups (intervention group only)
- Acceptability of Moms@Home – assessed through the End-user Mobile Application Rating Scale survey administered at 8 weeks, and the post-intervention focus groups (intervention group only)

Secondary outcome measures:

- Engagement with the Moms@Home mobile app will be measured by number of logins, time spent in the app, and storytelling videos watched (4, 8 weeks)
- BP measures - HBPM measures will be gathered from the Moms@Home app and paper BP diaries. Electronic health record review will be used to determine clinic BP values
- Medication adherence – change in medication adherence will be assessed through a brief survey (baseline, 4, 8 weeks)
- Goal attainment scaling - goal attainment will be rated using a 5-point goal attainment scale (baseline, 8 weeks)
- Physical activity - change in physical activity will be tracked by the FitBit (baseline, 4, 8 weeks)
- Moms@Home app sustainability measured with a short sustainability survey (4, 8 weeks)
- Healthcare utilization measures (ex. # of clinic visits, ED visits, admissions) and clinical outcome measures (ex. gestational age at delivery, preeclampsia) (baseline, 4, 8 weeks
- Self-efficacy measure using the self-efficacy for hypertension questionnaires (baseline, 4, 8 weeks)

Primary safety endpoints

- N/A

Secondary safety endpoints

- N/A

The primary outcome measures will be assessed using the Observed vs Expected number of HBPM readings recorded for participants over the study period. Group comparison will be done between the Moms@Home group vs ESC group.

11. PROCEDURES INVOLVED

Patients who are seen at the four UMass Memorial Health OB/MFM clinics in Worcester, MA will be recruited for the study. Participants will be recruited with the use of culturally sensitive recruitment materials and outreach plans vetted by the study's Patient Advisory Group (approved through STUDY00000395). Participants will be identified using a list generated by the Research Informatics core, through direct referrals from OB/MFM providers and community-based organizations via flyers, emails, and social media messages. Flyers (electronic and print) will be shared with community partners (e.g., Together For Kids Coalition, Worcester YMCA) via email or via hard copies. Community partnering organizations and individuals in the patient advisory group may post these flyers on their websites and social media platforms. Invitation letters will also be sent through MyChart (patient portal) and to home addresses 5–7 days before clinic visits with an opt-out link and phone number. Follow-up calls will be made to assess interest from people who do not respond to the invitations within 1-2 days before clinic visits. We aim to enroll 50% Black, Hispanic, and Asian pregnant individuals, as these populations need to be overrepresented to mirror disease presentation and achieve equitable representation.

Participants will be seen during their in-patient encounters or outpatient clinic visits to be consented if interested in the study and after providing more information about the study. After consenting, participants will then be randomized to Moms@Home arm or the ESC arm of the study using a permuted block randomization method stratified by clinic, in blocks of multiples of two. Those not providing consent will be asked a few questions to collect information on why they are declining participation.

A contact list of people declining to participate will be stored in Redcap and destroyed 6 years after study completion.

OB/MFM caregivers will be introduced to the Moms@Home approach and trained on the HBPM report (which will be delivered every 2 weeks during the study) at monthly OB/MFM department meetings and through job aids leading up to and during the start of the study.

Study arms:

Moms@Home intervention arm: Participants randomized to Moms@Home will receive the Moms@Home app (± Samsung smartphone), the digital BP monitor and cuff, and FitBit activity tracker. An orientation, FAQ sheet and HBPM pamphlets will include HBPM instructions, safety protocols, an introduction to the app, and tech support for the digital BP monitor, app, and FitBit. The FAQ sheet and HBPM pamphlet will be generated and submitted through a later modification of the IRB for approval before use. Participants randomized to the Moms@Home intervention arm will be helped by research staff to download and set up the MDH app and will be provided with a Bluetooth enabled blood pressure cuff and a FitBit that syncs with MDH .

Participants in the Moms@Home arm who do not have a smartphone, or have a limited data plan and prefer a study phone will be provided with a study smartphone, which they will return after their time on the study. Participants will each select personalization for daily notifications and set one personal goal. Participants will also be reminded to take daily home blood pressure measurements to be synced into the app.

Enhanced Standard Care (ESC) arm: Participants randomized to Enhanced Standard Care (ESC) will receive the digital BP monitor and cuff, a paper diary to record BP values, and a FitBit activity tracker. A modified orientation and FAQ sheet will include the same HBPM instructions, safety protocols, and tech support for the digital BP monitor and FitBit. Participants will each set one personal goal. Participants will also be reminded to take daily home blood pressure measurements to be recorded in the paper diary.

At home, over the 8-week RCT, participants will be instructed to measure their BP daily (2 readings, separated by 1 min) after a 3 min rest period. An HBPM video for reference will be part of the Moms@Home portal. The Moms@Home portal can be programmed with English or Spanish as default language and all videos will have Spanish subtitles. Traffic light (red, yellow, green) alerts and actions for abnormal BP values will be reviewed using a teach-back method. Participants will also be instructed to wear the study FitBit for daily activity and heart rate monitoring. Data from the FitBit will be transmitted through the MDH app to the study team for participants randomized to the intervention arm. For participants who are randomized to the enhanced standard care arm, de-identified physical activity i.e. daily steps, heart rate data and sleep data will be collected via encrypted methods through the FitBit app. Staff will be able to confirm data transmission prior to the participant heading home. The research team will call participants 1–3 days after their scheduled start to address any concerns, ensure data capture, and provide tech support.

Participant data will be collected at baseline (study entry) and the 8-wk follow-up in the privacy of the OB/MFM office (before or after clinic visits). Participants will be asked about their age, ethnicity/race, medication use, baseline HBPM use, and health literacy. If the 8-wk follow-up cannot be scheduled in person, this will be conducted over the phone or over Zoom. All 4-week follow-up visits will be done through a phone check-in. Study staff responsible for outcome assessment will be blinded to group assignments. Assessments will be pre-tested to ensure the time burden does not exceed 30 minutes.

Post-intervention focus group: After completing the 8-wk pilot test, three participant focus groups (intervention arm only, N=5/group, 1–1.5-hours) will discuss their experience and barriers/facilitators to engagement with Moms@Home.

Two focus groups with providers (N=5/group for a total of 10 providers, 1-hour) will focus on the home BP report experience, with one group of low utilizers and a second group of high utilizers of the electronic health record HBPM reports. Verbal consent for providers interested in focus group participation will be documented in Redcap.

All focus groups will be held at UMass if in-person (in the ACC building 4th floor conference room or the Memorial campus Peter Levine or 4-West conference room) or on Zoom depending on the schedules/preferences of the participants. These groups will be co-led by Dr. Kovell and a research coordinator trained in qualitative interviews. Both participant and provider semi-structured guides will be developed using the implementation measures of acceptability, appropriateness, and feasibility. The semi-structured guides will be submitted through a later modification of the IRB application for approval before the interviews are conducted. The focus group recordings will be uploaded to the password protected UMass Chan QMC network drive. Back-up copies of the video files will be stored in an external, password-protected hard drive and a Secure Digital (SD) card. Transcripts will be stored in the same hard drive and a password protected UMass Chan QMC network drive.

12. DATA AND SPECIMEN BANKING

All participants will be assigned a participant ID. Redcap and the Moms@Home app will be used for data collection and data banking. All digital data will be password protected and encrypted so that only research personnel can access stored data using the RedCap system.

We will create a master list linking the study IDs to identifiers which will be stored in RedCap. Access to this master list will be limited to only members of the study team members that need to work on this list. We will destroy the master list of identifiers 6 years after study completion. We may use the de-identified research data in other future research. We may also share de-identified research data with researchers that are not part of UMass Chan. In these cases, we will not share names or other details that directly identify participants.
Recordings from the focus groups will be destroyed after verification of notes. Detailed field notes, de-identified transcripts and linking documents, and codebooks will be maintained for 6 years after study closure. The study team will ensure the appropriate files are deleted from the external hard drive, QMC drive, and SD card as specified.

According to our study's data management and sharing plan (DMSP), de-identified human subjects' data from the study will be available in clinicaltrials.gov. "The final dataset will include de-identified self-reported demographic and behavioral data from participants and home blood pressure monitoring (HBPM) data from the Moms@Home app. If acceptable to NHLBI, we will work with the NHLBI BioData Catalyst (BDC) to deposit the appropriate data. Otherwise, this final dataset will be kept on hand and distributed upon reasonable request after an appropriate data-use agreement has been put in place. All data will be de-identified prior to release."

13. DATA ANALYSIS AND MANAGEMENT

Provide a power analysis and/or support for the sample size proposed for this study
Power calculations for this pilot trial are based on a 2-group, 2-sided Chi-square test of proportions with alpha=0.05. Assuming the intervention will improve HBPM adherence from 10% to 35% (based on our prior work with non-pregnant adults with HTN), we will achieve 80% power when the sample size is 43 per arm (N=86). We will recruit 100 participants to account for ~15% attrition. We base our proposed sample size also on pragmatic considerations related to recruitment, retention, and our focus on feasibility, providing important information for design and recruitment for a future R01 to test Moms@Home in a large RCT.

Describe the data analysis plan, including any statistical procedures

We will compare HBPM adherence (primary outcome) between the two arms (Moms@Home and ESC). Other outcomes (**see section 10**) will be compared using generalized estimating equations accounting for the appropriate distribution (e.g., binomial — dichotomous outcome such as HBPM adherence, or Poisson/Negative Binomial — count). We will quantify missing data and dropouts and examine reasons for ineligibility and discontinuation. All data distributions will be examined, and summary statistics calculated by group using an intention-to-treat approach. We will also include other potential modifiers of the intervention effect, potential confounders, and other covariates of interest. In the event of possible effect modification, we will explore the nature of the relationship through the use of interaction terms and subsequent subgroup analysis. This approach will be used for measures with pre-post measurements as well as those collected post-implementation only. Although the pilot study may not have adequate statistical power for testing our hypotheses of improved BP control and medication adherence, we will conduct an exploratory analysis of any treatment effects. We will also examine HBPM adherence by race/ethnicity. Per-protocol analysis will also be performed using all data available from randomized participants without replacement of missing data. Goal attainment scaling, step count, and sleep duration will be characterised for each participant, and then compared between the Moms@Home and ESC groups using a Wilcoxon-Mann-Whitney rank-sum test. In an exploratory analysis, we will compare HBPM, BP control, activity, frequency of visits, and pregnancy outcomes between the primary groups and subgroups (stratified by race/ethnicity, health literacy, income level, age, obesity, and trimester). Qualitative analyses will use applied thematic and content analysis for post-intervention focus groups. All quantitative analyses will be conducted using SAS 9.4 or STATA version 18. We will estimate relevant parameters including estimates of trial retention, intraclass correlation coefficient, standard deviation, and effect size for future R01 power calculations.

Describe any procedures that will be used for quality control and data security of collected data

- Principles underlying our approach to quality control include: (1) standardization of measurements and interventions; (2) use of clear and specific protocols for all activities, including training for data collection, intervention, and data processing; (3) validation and verification of all data collection and management procedures through data editing, double entry of data, bias detection (e.g., digit preference or unexpected runs) and use of software capable of checking for out-of-range values and other sources of outliers; (4) implementation of a data cleaning protocol which includes checks for consistency and examinations of frequency tabulations; and (5) regular meetings and progress reports to provide specific, well-documented feedback to the project personnel concerning potential difficulties as well as sufficient follow-up to ensure that problems are resolved in a timely fashion. Any changes to data sets resulting from these queries will be recorded through an electronic audit trail.

  All data activities will occur in the context of reproducible research. Specifically, datasets and analyses will be generated under documented protocols and standard operating procedures that allow other investigators to replicate findings. All variables will have

descriptive names and statistical programs will be annotated and archived, with the goal of making it easy to generate (and reproduce) research products.

Computerized data forms and other records will be kept in UMass Chan Redcap and a network QMC drive behind its firewall, where access is restricted to authorized personnel (with access through network username and password). Backup paper copies kept in a separate, secure location in locked cabinets in locked offices accessible only to research staff. Electronic data back-ups will be performed at least daily. To protect against inappropriate access, we will first handle and transmit only de-identified data wherever possible. Data transmissions will be handled over secure VPN connections or other secure procedures, and data will be encrypted wherever feasible. Analytic datasets will be stripped of patient identifiers, with re-identifying master lists kept in a separate, secure place.

- FitBit will have access to participant data from device (i.e. daily step count, heart rate and sleep data). When participant sign up for their FitBit account, they will agree to a privacy policy.(see here : Fitbit Legal: Privacy Policy). Each participant will be assigned a study ID and a study Fitbit login so that data is de-identified on export. FitBit is considered HIPAA approved and all information collected from device will remain confidential and will remain on secure servers.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

This study has minimal risks to subjects and adverse events are not anticipated, therefore, there is no data safety committee.

Study staff will monitor the Moms@Home platform twice daily and receive alerts for abnormal values (BP >140/90 mmHg). Study staff will call participants after the alert to ensure they reached the healthcare team or to direct participants to labor and delivery for severe elevations (BP >160/110 mmHg) or BP >140/90 mmHg with any preeclampsia symptoms. Similarly, we may encounter low BPs. For symptomatic systolic BP <90 mm Hg or DBP <50 mm Hg, participants will be instructed to call their OB/MFM office (symptoms, e.g., lightheaded, faint, experiencing vision changes, etc).

As is the current practice in the OB/MFM clinics, out of range blood pressures in the ESC group will be the responsibility of the participant to communicate them to their OB/MFM team. All participants will be given the phone number for the research staff to call in case there are questions about HBPM measures during business hours. Outside of business hours, the ESC participants will be instructed to report abnormal values by making a phone call or Epic MyChart message to their OB/MFM caregivers.

To protect participants against the risk of loss of confidential information, data abstractors will not be allowed to create or keep any other data records besides the formal records that will be created in the electronic data capture systems. We will obtain only the most limited personal identifiers as needed to accomplish the follow-up contact goals of the study, including patient name, email address, and other necessary information.

With regards to confidentiality, all patient data will be stored on a secure server accessed via encrypted devices only. All records with personal identifiers will be destroyed 6 years after completion of the study by shredding of the hard paper copy and destruction of the electronic files. Any participant with severe hypertension (described above in exclusion) will not be eligible for this study, and the participant's primary Obstetrician or MFM will be notified of the severe range blood pressure.

Although our study poses minimal risk to subjects and no adverse events are expected due to the nature of the study, we will follow the adverse event procedure of the UMass Chan Medical School. The current guidelines require that items meeting the criteria of prompt reporting (ex. harm experienced by a participant that is unexpected and probably related) will be reported to the IRB within 5 business days of the investigator becoming aware of the event.

15. Withdrawal of Subjects Without Their Consent

Subjects may withdraw from the study at any given time during the study period. Participants can withdraw at any time before or during the follow up visit phase, by requesting their data not be utilized. Subjects will not be withdrawn without their consent unless the study is cancelled.

16. Risks to Subjects

Minimal physical risk is involved in this study. The main risks to participants include 1) emotional reaction and stress in completing a health assessment and monitoring BP, 2) time taken to complete assessments/focus groups, and 3) potential breech of confidentiality of the collected individually identifiable data. We believe risks associated with participation in this research study to be minimal and of low likelihood.

Regarding the risk of subjects' personal information being lost or exposed, this is unlikely, and study staff will ensure to the best of their ability that information is protected. Given the risk of emotional reaction/stress to surveys, all participants will be taken through an overview of these surveys during the consent process to help them with their expectations of the surveys. The study Patient Advisory Board (as mentioned above) will be asked to vet and take sample surveys to ensure each survey does not exceed 30 minutes and surveys do not overwhelm study participants.

17. Potential Direct Benefits to Subjects

Participating in this RCT may increase understanding of the complications of hypertension and the value of home monitoring to improve blood pressure control to prevent these complications. There is no potential for benefit for participation in the focus groups. There is potential for improved BP control, self-efficacy, and BP awareness for patients who participate in this RCT.

18. Vulnerable Populations

Pregnant women

We will be enrolling women who are pregnant (please see section 6 for inclusion criteria) with the ability to consent to participate. There is no anticipated physical harm to the participant or the fetus.

Children
Children will not be included in this study.

Prisoners
Prisoners will not be included in this study.

Adults Unable to Consent
We will not include these patients in the study.

UMass Chan/UMass Memorial employees or students may participate in the RCT or focus groups. Their student status or employment would not be influenced in any way if they do or do not participate. No one in the study team directly supervises or is fully responsible for any employees, students, interns or residents who could potentially be enrolled in this study. If any obstetrics and gynecology residents or attendings, maternal fetal medicine fellows or attendings, or cardiology fellows partially supervised by the PI or co-investigators are possible participants, a 3rd party research assistant or research coordinator will be asked to consent to avoid any possible coercion or undue influence.

19. MULTI-SITE RESEARCH
NA

20. COMMUNITY-BASED PARTICIPATORY RESEARCH
We have partnered with the Community Engagement and Collaboration Core of the UMass Center for Clinical and Translational Science to convene a Patient Advisory Group (see above) to assist in study procedures as mentioned above.

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS
Home BP measure results will be shared with Moms@Home participants through the Moms@Home portal. See Section 11 for how results will be shared with participants and their health care providers. A brief end-of-study flyer with the main study findings will be sent to all interested participants when the study is complete.

22. SETTING
Subjects will be identified and recruited in the four OB/MFM clinics at UMass Memorial Hospital (mentioned above) from where they are referred and from the UMass Memorial Hospital inpatient service to enroll in the study. Consenting will happen in private rooms at the OB/MFM clinics or in private rooms in the hospital. Subjects will be given adequate time to have all their questions answered and to carefully consider participation. EHR data collection and chart review will be done in the investigators' private offices and in touch-down spaces in the clinic and hospital.

23. RESOURCES AVAILABLE
PI – The PI has led multiple research projects involving human subjects and has been involved in recruiting for several RCTs. The PI has training on clinical investigation and protection of human subjects through NIH coursework, time serving as an IRB committee member, and from

fellowship training. The PI will be overseeing each supporting role of the study personnel and ensure that the study team has appropriate CITI training. The PI will help recruit participants and manage the Redcap database. The PI will train the study staff on the study protocol, the process of consenting, and how to administer the surveys. The PI will plan to spend at least 1 hour per week on oversite of the staff and updating the Redcap database.

The **Co-Investigators** will assist the PI in research design and development, as well as analytic aspects and coding of the study. They will support in recruitment and informed consent procedures.

Research Coordinator – The Research Coordinator will oversee recruitment through communication with our community partners and OB/MFM clinicians. This person will assist the PI and the Co-Investigators in implementing all aspects of the project. The research coordinator will be responsible for working with the research assistants. The Research Coordinator will ensure that all study staff have appropriate CITI training and are aware of the most current study protocol. The research coordinator will spend on average 4 hours per week enrolling patients and updating the Redcap database.

Research assistants – The research assistants will be trained by the PI, co-investigators, or research coordinator on the protocol, the process of consenting, how to measure BP, and how to administer the surveys. Either the PI or co-investigators will demonstrate the consenting process with a participant and with the research assistant shadowing the process. They will be taught the process of informed consent. The research assistants will be taught to ensure that participants have a complete understanding of the purpose of the study, the surveys involved, the risks involved, and the demands placed upon them as a participant. They will be taught to determine capacity – the participant's ability to acquire and retain knowledge about the study, and the ability to understand the consequences of giving consent. The research assistants will help to design recruitment flyers. They will interface with the OB/MFM clinics to screen for appropriate participants for the study. They will be trained to consent with the support of an interpreter. The research assistants will spend on average 4 hours per week enrolling patients and updating the Redcap database.

Data analysts – will help manage the database on Redcap. They will help to input data into the Redcap database and analyze results. They will spend < 1 hour per week on the research process.

All personnel involved will be CITI-trained and trained by the PI or co-investigators on the research protocols and their specific duties and responsibilities. Therefore, they will be adequately informed about the protocol, research procedures, and their duties and responsibilities. Study staff will devote ample time to conducting and completing the study procedures.

24. LOCAL RECRUITMENT METHODS

Invitation letters will also be sent through MyChart (patient portal) and to home addresses 5–7 days before clinic visits with an opt-out link and phone number. Follow-up phone calls will be made to assess the interest of people who have not opted out and do not respond to the invitations 1-2 days before clinic visits. Participants will also be recruited through word of mouth

and flyers (see attached, with QR code to link to Redcap). We will provide these recruitment materials to our community partners (see section 11). They will have the option to post the flyer to social media groups relevant to their communities. Community partners will also post flyers on church and community boards in areas where they know there will be high traffic.

Participants will be screened for eligibility by study staff (see section 6).

Participants who do not opt out and are eligible will be seen during their clinic visits and given further information about the study, as well as potential risks and benefits. If the participant is interested, the consent form will be shared with them and a more detailed conversation regarding the risks and benefits of enrollment will be had. If consent is declined, the participant will be asked a few questions to collect information on why they are declining participation.

To recruit the 10 OB/MFM providers, we will reach out in person or through personal e-mail invitations to individual providers who see patients enrolled in the study. We will also attend department meetings to advertise the opportunity until we reach the target number, aiming for 5 high utilizers and 5 low utilizers (as described in section 11.)

A study stipend will be provided to all participants who complete the baseline ($25) and 4-week ($25) assessments. An additional $75 will be provided to participating subjects upon completion of the 8-week assessments and returning the BP monitor, FitBit, and Samsung phone (if applicable). Both arms of study participants will be eligible for these stipends, totaling $125. Moms@Home intervention group participants will be compensated $50 for completing the focus groups, and caregiver participants will be compensated $100 for completing focus groups.

25. LOCAL NUMBER OF SUBJECTS
We plan to enroll approximately 100 study participants for the RCT and 10 providers for the post-intervention provider focus groups (see section 11).

26. CONFIDENTIALITY
See sections 11, 12, and 13. De-identified data will be used whenever possible.

With this submission, we have requested a HIPAA waiver which will allow us to conduct medical records review to prescreen potential subjects for eligibility before approaching the patient. Since only minimal risks are involved in reviewing medical records, this will not adversely affect the rights and welfare of the patients. However, we will make our best effort to protect patient confidentiality. Data will be collected on password protected and encrypted iPads directly into RedCap and through the Moms@Home app with unique study ID for participants. The MDH platform has been used for other research studies and has provided adequate protection for participant data collection.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS
We have requested HIPAA waiver which will allow us to conduct medical records review to prescreen potential research subjects for eligibility before approaching the subject. Since only minimal risks will be involved for reviewing medical records, this will not adversely affect the rights and welfare of the subjects. Recruitment will take place solely in a private setting.

Participants will be informed that participation is voluntary, and participants can change their mind at any time. The collection of any personal information will be limited to information necessary to conduct this research. Consent will be collected for all participants.

The CITI-certified personnel will comply with HIPAA privacy rule to protect patients' health information and confidentiality of personal information. Data will be entered into a secure RedCap database with a unique study ID (as described above in #26).

28. COMPENSATION FOR RESEARCH-RELATED INJURY
This is a minimal risk study and will not have physical risks involved, therefore, no funds for compensation for research-related injury have been set aside. The following is in the ICF form, directed to the patient:

"The University of Massachusetts Medical School does not provide funds for the treatment of research-related injury. If you are injured because of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by participating in this research. "

29. ECONOMIC BURDEN TO SUBJECTS
NA.

30. CONSENT PROCESS
All staff will be trained by the PI or one of the co-investigators on how to consent (see section 23 and 24). All staff will be provided with copies of the HRP- 090- SOP- Informed Consent Process for Research and HRP-091-SOP- Written Documentation of Consent pdfs. The consent process will take place in a private clinic or hospital room. All participants will be allowed extra time to read the consent form through if interested. If a waiting period is requested by a potentially interested participant, they will be asked at subsequent clinic visits to participate. The consent document will include a number that participants can call if they change their mind about participation. We will clearly indicate that participation in the study is voluntary and is not going to affect the patient's treatment plan. Informed consent through a RedCap e-consent with electronic signature field, with a back-up option of written informed consent depending on patient preference, will be sought for all RCT participants, and verbal consent as above for provider focus groups (see section 11).

We will be obtaining consent for Spanish speaking subjects with the help of UMMH clinical interpreters and there will be an impartial witness (who understands both languages) present when an interpreter is used. We will have a short Spanish form with UMMS IRB approval for Spanish language speakers. We do not anticipate a significant population of Spanish speaking subjects based on enrollment in our intervention development studies. If we enroll more than 3 Spanish speakers, we will translate the long-form consent and surveys into Spanish.

31. PROCESS TO DOCUMENT CONSENT IN WRITING
Consenting documentation will be scanned into EPIC.
Verbal consent will be documented in Redcap (see section 11).

32. DRUGS OR DEVICES

This is not an IDE, IND, or abbreviated IDE study.The FitBit and its software does not qualify as a medical device according to the FDA guidance.

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