

PROTOCOL TITLE:

HEART at Home: Improving Postpartum Cardiovascular Outcomes through Implementation of a Hybrid Home-Based and Remote Blood Pressure Management Model for Hypertensive Disorders of Pregnancy

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1. BACKGROUND

Maternal mortality in Missouri is the seventh highest in the US, with cardiovascular disease - particularly among women with hypertensive disorders of pregnancy (HDP) - as the leading cause of maternal death.¹⁻³ 82% of maternal deaths occur between 6 and 52 weeks postpartum, yet obstetric care typically ends at 6 weeks.^{1,4} The American Heart Association recommends cardiovascular risk assessment and transition of care to a non-obstetric provider at 8-12 weeks and ensuring care up to 12 months postpartum.⁵ However, existing models of postpartum care remain structurally clinic-dependent during the first postpartum year, despite well-documented and persistent structural, clinician-, and patient-level barriers.⁶⁻⁸ This leads to markedly low routine postpartum clinic follow-up rates, across socioeconomic strata and even amongst individuals with hypertensive disorders of pregnancy (HDP), where follow-up rate is as low as 25% at 6-12 weeks postpartum.^{6,7,9-11} These gaps persist despite expanded use of clinic-anchored remote blood pressure monitoring (rBPM), which is largely limited to the first 2–6 weeks postpartum and does not support longitudinal care.¹²⁻¹⁵ In our 5-year pilot study of a 14-day postpartum rBPM program among women with HDP at Barnes-Jewish Hospital, 68% remained hypertensive at the end of the monitoring period without a defined follow-up pathway, despite high intervention uptake (93% completed ≥ 10 of 14 readings). Women with the highest risk HDP - preeclampsia with severe features - and Black women, had significantly higher rates of persistent hypertension and hospital readmission within 6 weeks postpartum.

Home visiting represents a promising but underutilized care delivery strategy that provides higher-touch support—characterized by more frequent points of contact and associated with improved clinical outcomes and cost-effectiveness in managing chronic medical conditions—through tailored, one-to-one engagement integrating education, behavior change, and linkage to clinical care.¹⁶⁻²¹ The national home visiting organization Parents as Teachers (PAT) offers an established, scalable infrastructure and reimbursable workforce with a strong rural footprint.^{22,23} Furthermore, because visits are reimbursed for high-risk families by design, this model represents a cost-effective platform for delivering care to medically high-risk populations.²³ In our analysis of a 47,000-participant national PAT dataset, routine postpartum clinic attendance was only 30%, including among high-risk pregnancies and particularly in rural settings, while earlier and consistent home visiting was associated with improved postpartum care engagement. Overall, care delivery is fundamentally misaligned with the timing and magnitude of maternal health risk, creating a critical implementation gap. This career development award will address this gap by piloting a hybrid model that integrates telehealth monitoring with targeted home-visiting–based education and care navigation.^{24,25}

2. OBJECTIVES

This protocol describes a single-arm pilot feasibility trial to evaluate the feasibility, fidelity, and acceptability of integrating:

1. postpartum remote blood pressure monitoring with telehealth-based medication management through 12 weeks postpartum, and
2. home-visiting–based monitoring and education delivered on a twice-monthly basis through the Parents as Teachers (PAT) National Home Visiting program.

The long-term objective is to develop a feasible, acceptable, and scalable evidence-based postpartum hypertension intervention that can be expanded nationally through the PAT home visiting network for individuals with hypertensive disorders of pregnancy (HDP).

3. AIMS

Primary Aim:

To evaluate the feasibility, fidelity, and acceptability of incorporating remote blood pressure monitoring with telehealth clinical management into an established home visiting framework from weeks 3–12 postpartum in patients with HDP (n = 10).

Secondary Aim:

To describe clinical process outcomes, including blood pressure treatment and medication adjustments, during the intervention period.

We hypothesize that a home-visiting–based remote blood pressure monitoring program will be feasible, implemented as intended, and acceptable among patients, clinicians, and home visitors, and will support early identification and management of persistent postpartum hypertension ($\geq 130/80$ mm Hg).

4. STUDY DESIGN AND PROCEDURES

4.1 Study Design

This is a single-arm pilot feasibility study. A comparator group is not included because the standard of care comparator consists of routine postpartum follow-up alone (typically a single clinic visit at approximately 6 weeks postpartum), and the primary purpose of this pilot is to assess feasibility, fidelity, and acceptability rather than clinical effectiveness.

4.2 Sampling and Recruitment

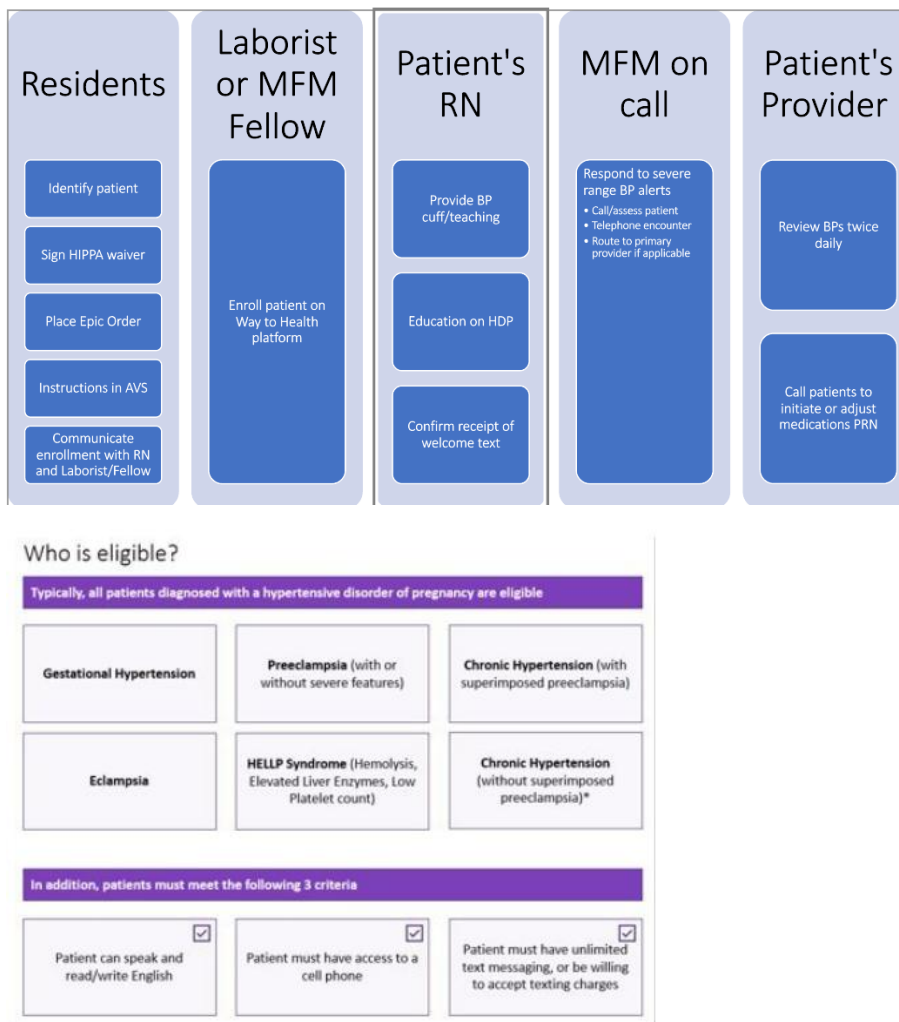
An existing remote blood pressure monitoring (rBPM) program for patients with HDP is in place at Barnes Jewish Hospital. Patients with a diagnosis of HDP—including chronic hypertension, gestational hypertension, preeclampsia, eclampsia, HELLP syndrome, or chronic hypertension with superimposed preeclampsia—are enrolled in rBPM at the time of delivery prior to hospital discharge.

Within this program, patients submit blood pressure measurements twice daily for 14 days postpartum through the Way To Health platform, with alerts managed by an advanced practice provider. Details of enrollment criteria and systems-level management for the rBPM program are outlined in Figure 1.

Patients who remain persistently hypertensive (systolic BP ≥ 130 mm Hg or diastolic BP ≥ 80 mm Hg) at the conclusion of the 14-day rBPM period will be invited to enroll in this pilot study and concurrently enrolled in the Parents as Teachers home visiting program, which is voluntary and provided at no cost.

Target sample size: 10 participants.

Figure 1. Enrollment and Eligibility for Existent rBPM program at Barnes Jewish Hospital



4.3 Eligibility Criteria

Inclusion Criteria

- Age ≥ 18 years
- Enrollment in the Barnes Jewish Hospital rBPM program; as per eligibility criteria above, patient has a physician-made diagnosis of HDP per American College of Obstetricians and gynecologists criteria
- Measured at least 4 days of blood pressure during initial program
- At least one blood pressure was made after monitoring day 7
- Confirmed at least two separate blood pressure $\geq 130/80$ mm Hg at the end of the 14-day rBPM period

- Ability and willingness to participate in home visits and remote monitoring
- Able to communicate in English without the need for interpretation services

Exclusion Criteria

- Inability to provide informed consent
- Physician determination of inability to measure blood pressure at home due to comorbidities or other limiting conditions
- No access to a phone

To promote equitable participation, home visitors will tailor education for individuals with low digital literacy, and blood pressure cuffs will be supplied to all participants.

4.4 Consent Process

The principal investigator or study coordinator will identify eligible participants at the completion of the 14-day rBPM program. Study procedures, risks, and benefits will be explained, and participants will be given the opportunity to ask questions.

Written informed consent will be obtained prior to any study-related procedures. For participants unable to sign due to physical disability or illiteracy, verbal consent with a witness and a thumbprint in lieu of signature will be obtained. A copy of the consent form will be provided to all participants.

4.5 Intervention

Participants will be enrolled at the conclusion of the standard 14-day postpartum rBPM program and followed from weeks 3 through 12 postpartum. Because the rBPM program starts after hospital discharge (which is most common postpartum day 5), the program will start at postpartum week 3.

4.5.1 Baseline Assessment

Participants will complete a telephone-based questionnaire to collect demographic information, medical history, current medications, and patient-reported postpartum health using selected Patient-Reported Outcomes Measurement Information System (PROMIS®) measures assessing physical, mental, and social health domains relevant to the postpartum period. PROMIS measures were selected to minimize respondent burden while capturing key domains of postpartum health, including physical function, fatigue, emotional distress, sleep disturbance, and social role participation. The questionnaire is included in **Appendix 1**.

4.5.2 Parents as Teachers Home Visiting

Participants will receive three in-person home visits conducted by trained PAT home visitors at approximately 4, 8, and 12 weeks postpartum, consistent with the standard PAT service delivery model.

During home visits, home visitors will:

- Assess symptoms and interval health events
- Provide education on healthy behaviors and principles of blood pressure management and warning signs of severe hypertension
- Provide hands-on assistance with proper blood pressure measurement technique
- Support medication adherence
- Facilitate transition of care to a primary care provider or cardiologist at the 12-week visit, as appropriate, using existing PAT care linkage processes

Between in-person visits, PAT home visitors will conduct remote check-ins via text message or telephone, consistent with established PAT practice, to provide ongoing support and engagement. These remote touchpoints will be tracked.

4.5.3 Remote Blood Pressure Monitoring Frequency

Participants will continue home blood pressure monitoring following completion of the standard 14-day postpartum remote blood pressure monitoring program. Measurement frequency will be down-titrated over time based on blood pressure stability, consistent with prior postpartum hypertension monitoring protocols^{26,27} and minimizing participant burden while maintaining safety.

Postpartum Weeks 3–4: daily BP readings

Postpartum Weeks 5–8: 3–4 days per week

- Eligibility to down-titrate:
 - Blood pressure consistently <140/90 mm Hg
 - No severe-range blood pressures
 - No recent medication escalation

Postpartum Weeks 9–12: 1–2 days per week

- Eligibility to down-titrate:
 - Blood pressure consistently <130/80 mm Hg or clinically stable per provider assessment
 - No medication changes within the prior 2 weeks

Re-Escalation Criteria: Participants will be instructed to increase measurement frequency to daily and home visitors or participants will notify the clinical team if any of the following occur:

- Any severe-range blood pressure ($\geq 160/110$ mm Hg)
- New or worsening symptoms suggestive of hypertensive complications

- Medication initiation or dose adjustment

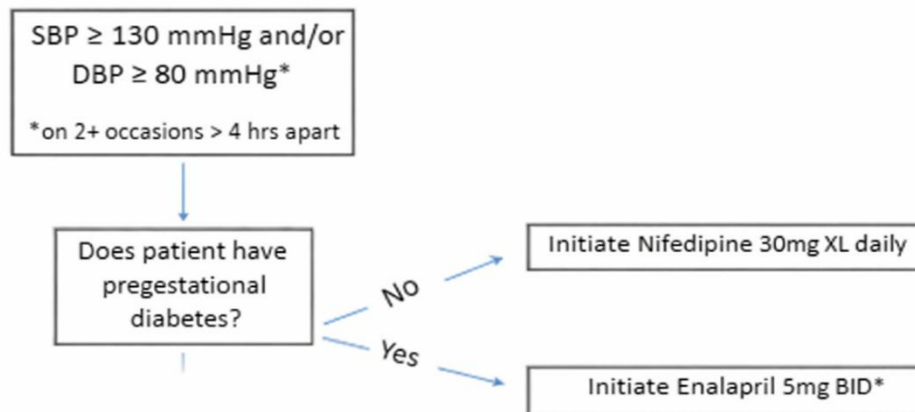
Clinical teams may modify monitoring frequency at any time based on clinical judgment.

4.5.4 Medication Management

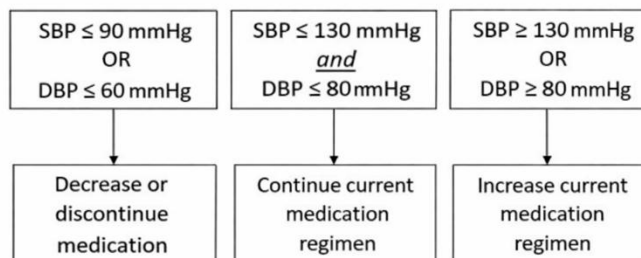
Medication management is protocolized (Figure 2) and carried out by an advanced practice provider or physician with prescribing authority, with clinician discretion applied when evaluating trends or identifying erroneous measurements.

Figure 2. Medication Management

For patients not on anti-hypertensive therapy:



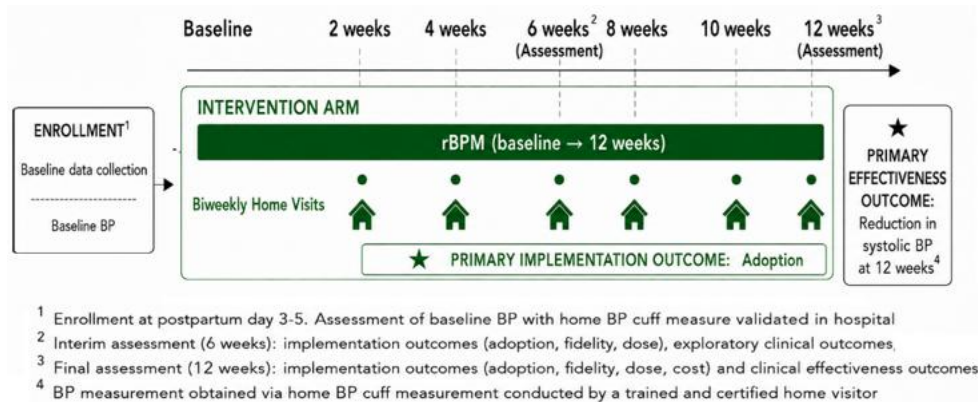
For patients already on anti-hypertensive therapy:



Severe-range blood pressures (systolic ≥ 160 mm Hg or diastolic ≥ 110 mm Hg) will trigger protocolized escalation, including coordination with PAT home visitors to speak with a medical provider and facilitate emergency department evaluation when indicated.

Figure 3 shows the overall study schema.

Figure 3. Study Schema



5. STUDY OUTCOMES

Outcomes		Outcome Definition/Measure
Primary Implementation Outcome – Adoption		≥ 1 home visit completed with BP measurement and transmission to clinical team
Secondary Implementation Outcomes	Reach	Recruitment rate over study period
	Fidelity	Completion of three scheduled in-person home visits and participation in remote BP monitoring during the intervention period, with appropriate escalation of abnormal BP or symptoms
	Time-Based Cost	Additional time required to deliver intervention components during home visits
Primary Clinical Outcome	Reduction in Systolic BP	Assessed at 6 and 12 weeks postpartum

	Reduction in Diastolic BP	Assessed at 6 and 12 weeks postpartum
Secondary Clinical Outcomes	Blood pressure Control	Proportion of participants with BP <130/80 mm Hg at 6 and 12 weeks postpartum
	Number of medication adjustments	Any initiation, discontinuation, dose change, or change in antihypertensive medication during weeks 3–12 postpartum.
Exploratory Outcomes	Number of unplanned care utilization events (ED visits or hospital readmissions)	

**Safety
Outcomes**

The incidence of serious adverse events (overall) and cardiovascular specific SAEs (all-cause cardiovascular hospital readmission, postpartum pre-eclampsia, hypertensive urgency/emergency, stroke, heart failure/pulmonary edema, seizure and mortality) at 12 weeks postpartum.

Adverse events of special interest: syncope, dizziness/lightheadedness, acute kidney injury, edema

6. DATA MANAGEMENT AND CONFIDENTIALITY

Data collected during home visits will be entered into the Parents as Teachers central data management system. Clinical data, including blood pressure trends and medication adjustments, will be stored in Washington University's REDCap system. All data will be handled in accordance with institutional confidentiality and security policies.

8. FEASIBILITY AND ALTERNATIVE STRATEGIES

Potential challenges include participant acceptability of home visits and coordination across clinical and community-based teams. These will be addressed through clear role delineation, established PAT communication practices, and regular interdisciplinary coordination.

9. POTENTIAL BENEFITS, RISKS, AND WITHDRAWAL

Participants may benefit from improved blood pressure monitoring, education, and timely medication adjustments. Risks include potential medication side effects, which will be managed by the participant's clinical care team.

Participants may withdraw at any time. Data collected prior to withdrawal will be retained unless the participant requests removal. Participants may also be withdrawn if continuation is deemed unsafe by the clinical team.

10. DISSEMINATION OF RESULTS

Results will be shared with participants and stakeholders through community forums, conference presentations, and peer-reviewed publications. If feasible and acceptable, the intervention will be expanded to additional sites and potentially implemented nationally through the PAT network.

11. COMPENSATION

Participants will receive USD 50 at the end of the 12 weeks period for participation in the extended remote blood pressure monitoring program.

12. DATA ANALYSIS

Descriptive statistics will summarize feasibility, fidelity, acceptability, and clinical process outcomes. Time-in-target blood pressure will be calculated as the proportion of days with BP <130/80 mm Hg during the intervention period. Retention will be defined as completion of study activities through week 12 postpartum. Participants lost to follow-up will be retained in analyses as loss-to-follow-up events.

As a pilot feasibility study, this trial is not powered to detect differences in clinical outcomes.

Appendix A. Participant Questionnaire

Administration: Telephone-based

Timeframe: Baseline (enrollment) and 12 weeks postpartum unless otherwise specified

A. Demographics

1. Age
 2. Race
 3. Ethnicity
 4. Highest level of education completed
 5. Insurance type
 6. Employment status
 7. Number of prior births
 8. Current living situation (alone, with partner, with family, other)
-

B. Pregnancy and Delivery History

1. Hypertensive disorder during pregnancy (select all that apply):
 - Chronic hypertension
 - Gestational hypertension
 - Preeclampsia
 - Preeclampsia with severe features
 - Eclampsia
 - HELLP syndrome
 - Chronic hypertension with superimposed preeclampsia
2. Gestational age at delivery
3. Mode of delivery (vaginal / cesarean)
4. Did you experience any of the following pregnancy or delivery complications? (yes/no; specify):
 - Gestational diabetes
 - Postpartum hemorrhage
 - Infection

- ICU admission
 - Other (free text)
-

C. Medical History

1. History of chronic hypertension prior to pregnancy (yes/no)
 2. History of cardiovascular disease (yes/no; specify)
 3. History of diabetes (pre-gestational or gestational)
 4. History of kidney disease (yes/no)
 5. Other chronic medical conditions (free text)
-

D. Current Medications

1. Are you currently taking any medications? (yes/no)
 - If yes, list each medication with dose and frequency
 2. Are you currently taking medication for blood pressure? (yes/no)
 - Name(s) of medication(s)
 - Dose and frequency
 - Date started
 3. In the past 7 days, have you missed any doses of your blood pressure medication? (yes/no)
 4. Have you experienced any side effects from your blood pressure medication? (yes/no; specify)
-

E. Blood Pressure Monitoring Experience

1. How confident do you feel measuring your blood pressure at home?
 - Very confident / Somewhat confident / Not confident
 2. Have you had difficulty using the blood pressure cuff or monitoring app? (yes/no; specify)
 3. Do you feel you understand when to seek medical care for high blood pressure? (yes/no)
-

F. Postpartum Health – PROMIS Measures (Past 7 Days)

PROMIS General Health

Please answer the following questions based on your health over the past 7 days.

1. In general, would you say your health is:
 - Excellent / Very good / Good / Fair / Poor
2. In general, would you say your quality of life is:
 - Excellent / Very good / Good / Fair / Poor
3. In general, how would you rate your physical health?
 - Excellent / Very good / Good / Fair / Poor
4. In general, how would you rate your mental health, including mood and ability to think?
 - Excellent / Very good / Good / Fair / Poor
5. In general, how would you rate your satisfaction with social activities and relationships?
 - Excellent / Very good / Good / Fair / Poor
6. To what extent are you able to carry out your everyday physical activities?
 - Completely / Mostly / Moderately / A little / Not at all
7. How well are you able to carry out your usual social activities and roles?
 - Excellent / Very good / Good / Fair / Poor
8. In the past 7 days, how would you rate your pain on average?
 - 0 (No pain) to 10 (Worst imaginable pain)
9. In the past 7 days, how often were you bothered by emotional problems such as feeling anxious, depressed, or irritable?
 - Never / Rarely / Sometimes / Often / Always
10. In the past 7 days, how would you rate your fatigue on average?
 - None / Mild / Moderate / Severe / Very severe

PROMIS Anxiety Short Form (4a)

In the past 7 days...

1. I felt fearful
2. I found it hard to focus on anything other than my anxiety

3. My worries overwhelmed me
4. I felt uneasy

Response options:

- Never / Rarely / Sometimes / Often / Always

PROMIS Fatigue Short Form (4a)

In the past 7 days...

1. I felt fatigued
2. I had trouble starting things because I was tired
3. I felt run down
4. I had trouble finishing things because I was tired

Response options:

- Never / Rarely / Sometimes / Often / Always

PROMIS Sleep Disturbance Short Form (4a)

In the past 7 days...

1. My sleep quality was poor
2. My sleep was restless
3. I had trouble sleeping
4. I had difficulty falling asleep

Response options:

- Not at all / A little bit / Somewhat / Quite a bit / Very much

G. Postpartum Depression – Edinburgh Postnatal Depression Scale (EPDS)

Instructions:

Please choose the response that best describes how you have felt during the past 7 days, not just today.

1. I have been able to laugh and see the funny side of things

- As much as I always could
- Not quite so much now

- Definitely not so much now
 - Not at all
-

2. I have looked forward with enjoyment to things

- As much as I ever did
 - Rather less than I used to
 - Definitely less than I used to
 - Hardly at all
-

3. I have blamed myself unnecessarily when things went wrong

- Yes, most of the time
 - Yes, some of the time
 - Not very often
 - No, never
-

4. I have been anxious or worried for no good reason

- No, not at all
 - Hardly ever
 - Yes, sometimes
 - Yes, very often
-

5. I have felt scared or panicky for no very good reason

- Yes, quite a lot
 - Yes, sometimes
 - No, not much
 - No, not at all
-

6. Things have been getting on top of me

- Yes, most of the time I haven't been able to cope at all
 - Yes, sometimes I haven't been coping as well as usual
 - No, most of the time I have coped quite well
 - No, I have been coping as well as ever
-

7. I have been so unhappy that I have had difficulty sleeping

- Yes, most of the time
 - Yes, sometimes
 - Not very often
 - No, not at all
-

8. I have felt sad or miserable

- Yes, most of the time
 - Yes, quite often
 - Not very often
 - No, not at all
-

9. I have been so unhappy that I have been crying

- Yes, most of the time
 - Yes, quite often
 - Only occasionally
 - No, never
-

10. The thought of harming myself has occurred to me

- Yes, quite often
- Sometimes
- Hardly ever
- Never

If patient scores >10, please call the maternal hotline.

H. Program Acceptability (12-Week Assessment Only)

1. Overall, how satisfied were you with the program?
 - Very satisfied / Satisfied / Neutral / Dissatisfied / Very dissatisfied
 2. Would you recommend this program to another postpartum patient with high blood pressure?
 - Definitely yes / Probably yes / Probably no / Definitely no
 3. Which parts of the program were most helpful? (select all that apply):
 - Home visits
 - Remote check-ins (text/phone)
 - Blood pressure monitoring
 - Medication management
 4. What challenges did you experience during the program? (open-ended)
-

I. Visit Completion and Follow-Up

1. Home visit completed at:
 - Week 4 (yes/no)
 - Week 8 (yes/no)
 - Week 12 (yes/no)
2. If the program was discontinued early, what was the primary reason? (unable to contact, withdrew, other)

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