Blood Pressure Checks for Diagnosing Hypertension (BP-CHECK)

PROTOCOL

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This protocol was submitted to and approved (IRBNet #957723) by the Kaiser Permanente Washington Human Subjects Review Committee prior to contacting and enrolling. A detailed description of the BP-CHECK study design and methods has been published.
https://www.ncbi.nlm.nih.gov/pubmed/30634036

1. Objectives:

- **Aim 1:** To compare the accuracy of clinic, home, and kiosk BP to 24-hour ambulatory BP (reference standard, referred to as 24-hour BP) for new hypertension diagnoses. Our primary outcome is differences in mean systolic and diastolic BP comparing clinic, home, and kiosk to 24-hour BP. Secondary outcomes include sensitivity and specificity of clinic, home, and kiosk compared to 24-hour BP and heterogeneity of mean BP differences by patient characteristics (e.g., age, race, baseline BP, body mass index [BMI]). We hypothesize that home BP and kiosk BP will be accurate compared to 24-hour BP, and more accurate than clinic BP.
- **Aim 2:** To compare the acceptability of clinic, home, kiosk, and 24-hour BP diagnostic testing. Outcomes include percent of patients who complete their assigned testing regimen, acceptability (e.g., ease, convenience, confidence with), and adverse events (e.g., anxiety, loss of sleep, pain, disruption of activities). We hypothesize that patients will adhere to clinic, home, and kiosk BPs protocols and they will prefer these to 24-hour BP.
- **Aim 3:** To compare 6-month patient-reported outcomes (e.g., anxiety, health-related quality of life, and behavior change) and BP outcomes after the diagnostic period, (intermediate outcomes), by assigned diagnostic group and by whether hypertension is confirmed or ruled out. We hypothesize that patients will experience short-term distress related to high BP during the diagnostic period, but that this will resolve by 6 months.
- **Aim 4:** To examine provider (physicians, nurses, and MA) and organizational leaders' knowledge, preferences, and beliefs about BP diagnostic tests pre and post study and identify implementation barriers and facilitators for clinic, home, kiosk, and 24-hour BP monitoring.

2. Background:

Almost one in three Americans have hypertension sustained high blood pressure (BP). Hypertension[1] is the leading risk factor for cardiovascular disease (CVD) and CVD is the most common cause of avoidable death and disability in the U.S.[2] Hypertension is the most common diagnosis at clinic visits and accounts for over half of diagnoses in adults with chronic conditions.[3] While the majority of adults with hypertension are on treatment, more than one in three people with the condition may be unaware.[4]

The US Preventive Services Task Force (USPSTF) strongly recommends screening all adults for hypertension.[5,6] The USPSTF also recommends that before a diagnosis of hypertension is made, it should be confirmed with out-of-office BP measurements with 24-hour ambulatory monitoring (24-hour BP) preferred, but home BP monitoring as an acceptable option. Between 5-65% of patients with high BP in clinic have normal BP when measured by 24-hour ambulatory BP monitoring (24-hour BP). The USPSTF found strong evidence that 24-hour BP predicts CVD events and death, and moderate evidence supports home BP, while clinic BPs do not predict these events. They also called for more research on BP kiosks, such as those commonly found at drug stores, and their potential use in confirming a new diagnosis of hypertension.

Confirming new hypertension diagnoses with out-of-office 24-hour or home BP monitoring could avoid over-diagnoses and harms such as unnecessary treatments and mislabeling patients with a chronic condition. However currently, clinicians rarely order 24-hour BP monitoring.[7] They sometimes use home BP monitoring, but not according to protocols recommended for diagnosing hypertension. Patients with

hypertension or occasional high BP measurements wanted to know their true, average BP outside of clinic. They worry about strokes and want to control BP if it is high but avoid medication if it is normal.

3. Study Design Overview:

We will identify patients aged 18-85 with high BP at their last clinic visit and invite them to a screening visit. Patients with high BP at the screening visit and consenting to participate will be randomized to (1) Clinic BP, (2) Home BP, or (3) Kiosk BP diagnostic groups for confirming a new diagnosis of hypertension. Participants will complete their diagnostic tests over 3 weeks. They will then be asked to complete 24-hour BP monitoring. Participants will complete surveys at baseline prior to randomization, before and after diagnostic tests, and at 6 months. We will also assess provider knowledge, beliefs, and preferences about hypertension diagnostic tests. We will conduct qualitative interviews with patients and providers to assess their views on the different BP measurement regimens and how they interpret BP measurement and hypertension diagnostic testing.

3.a. Study Flow:

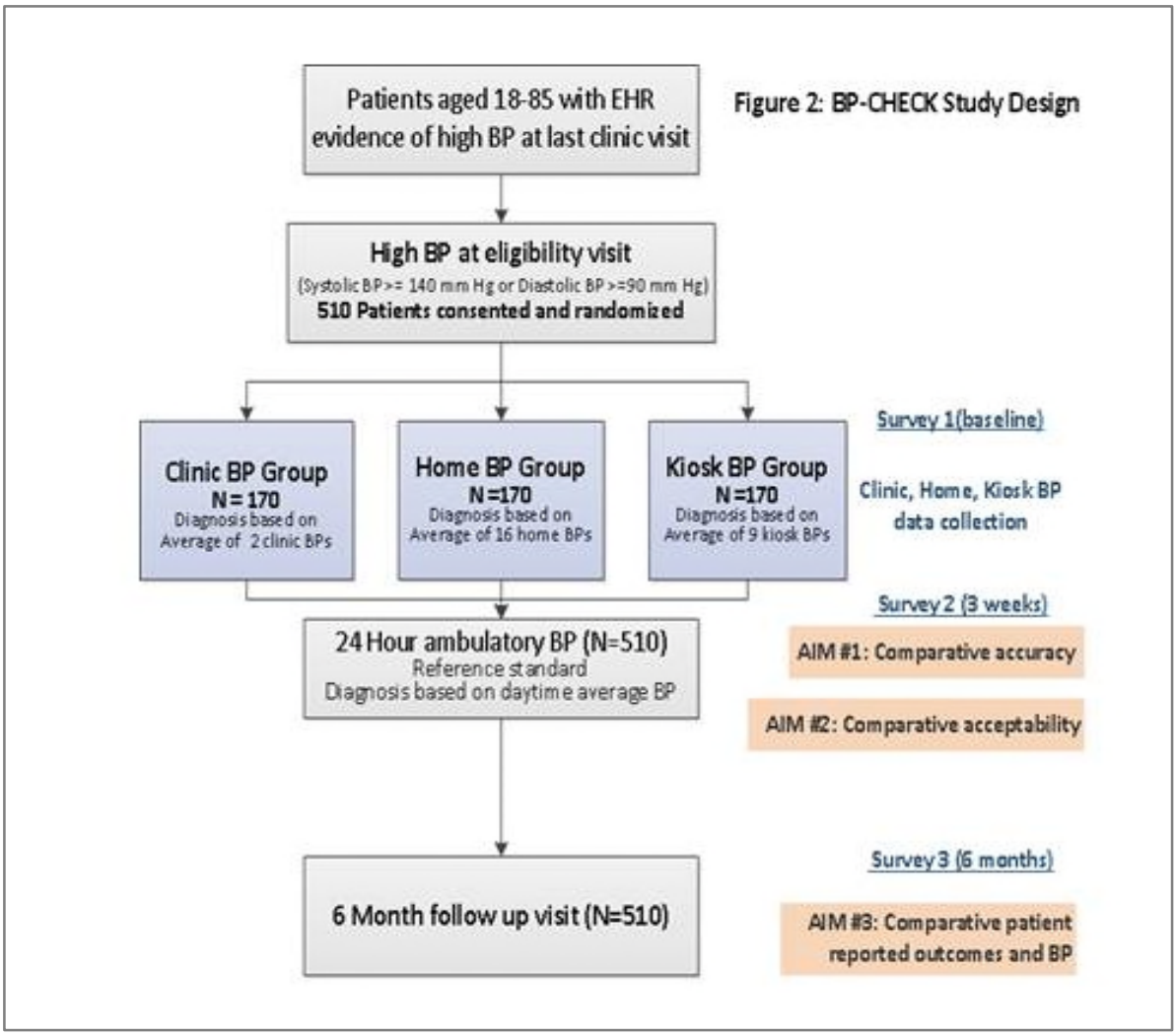

Figure 2: BP-CHECK Study Design

3.b. Study Timeline:

Enrollment, Diagnostic Intervention, and Outcome Assessment Schedule:

STUDY PERIOD					
	Enrollment	Randomization			
TIMEPOINT	-T1	T0 (Visit 1)	Visit 2	Visit 3	Visit 4
			3 weeks	3 weeks + 1 day	6 months
ENROLLMENT					
Phone eligibility screen	X				
In-person eligibility screen	X				
Informed consent	X				
Randomization/allocation		X			
DIAGNOSTIC INTERVENTIONS					
Clinic BP		X – – – – –	X		
Home BP		X – – – – –	X		
Kiosk BP		X – – – – –	X		
ASSESSMENTS					
Baseline data (EHR data, eligibility questions)	X	X			
Clinic, home, kiosk BP data by group			X		
24-hour ambulatory BP (all groups)				X	
Biometric data (research BPs, weight, height, arm size)	X				X
Surveys (patient-reported outcomes)	X	X	X	X	X
EHR data (hypertension diagnosis)					X
QUALITATIVE ASSESSMENTS (Participants)				X	X
PROVIDER SURVEYS AND INTERVIEWS	X			X	

4. Study Population:

4. a. Study Setting:

BP-CHECK is a single site study that will be conducted at Kaiser Permanente in Western Washington, at approximately 10-12 Kaiser Permanente owned primary care medical centers. We will oversample clinics with higher proportion of non-whites because they are disproportionally affected by high BP, lack of awareness, treatment and control of hypertension, and have worse cardiovascular disease outcomes.

We plan to do study screening visits and follow-up research visits at the patient's regular clinic or one nearby, making it more convenient for patients to participate and our results more real-world, as hypertension is currently diagnosed at clinic visits. We have used similar procedures in two prior hypertension studies, e-BP and e-Care for Heart Wellness.

4.b. Inclusion and Exclusion Criteria

We will use Electronic Health Record (EHR) data to identify KPWA members aged 18–85 who at last clinic visit had a high BP ($\geq$138 mm Hg systolic or $\geq$88 mm Hg diastolic) with no history of hypertension diagnosis in the prior 2 years and no antihypertensive medication use in the prior 12 months. We will exclude patients with very high BPs (systolic $\geq$180 mm Hg or diastolic $\geq$110 mm Hg), severe life-limiting illness (e.g., hospice, Alzheimer's disease), and with atrial fibrillation in the last 4 years and other significant arrhythmias (e.g., pacemaker use) because automated device BP measurements may not be as accurate for them, patients with end stage renal disease or on dialysis as BP care is different for

this population, and patients with a diagnosis of psychosis as they may not be able to compete study procedures, as well as patients with conditions such as amputation, paraplegia, lymphedema, shunt that would make it difficult for them to measure their BP at home or with a BP kiosk. Children and pregnant women will not be included as their recommendations for diagnosis of high BP are different.

Data Source	**EHR and Administrative Data**	**Date Range**	**Self Report**	**Screening Visit**
Inclusion Criteria				
Aged 18-85 at time of sample	X	Sample date		
Enrolled at GH for at least 2 years*	X	Prior 2 years		
Assigned to a PCP at participating GH clinic	X	Sample date		
High BP (systolic ≥138 or diastolic ≥88 mm Hg) at last ambulatory visit (primary care, urgent care, specialty)	X	Last visit with a BP		
No hypertension diagnostic codes in EHR for 2 yrs.	X	Prior 2 years		
No hypertension medications last 12 months	X	Prior 12 months		
Able to converse and read in English			X	
Planning to stay in the health plan for the next 6 mos.			X	
Able to come to a research visit (at their clinic) 2-3 weeks after enrolling in the study and at 6 months			X	X
Mid upper arm size 22 – 42 cm				X
High BP at screening visit (BP taken 2 times, high each time)				X
*Medicaid patients are enrolled with Molina Insurance and not -Kaiser Permanente Insurance, thus enrollment is defined as being on the -Kaiser Permanente Molina registry and having a primary care visit in a participating clinic in the prior 2 years.				

Data Source	EHR and Administrative Data	Date Range	Self Report	Screening Visit
Exclusion Criteria				
On no contact list	X			
Pregnant or planning to become in the next 6 months			X	X
Unable to converse or read in the English language			X	X
Atrial fibrillation	X	Prior 2 years		
Pacemaker	X	Ever		
Defibrillator	X	Ever		
Hospice	X	Prior year		
Nursing home	X	Prior year		
Dementia	X	Ever		
Psychiatric conditions with psychosis	X	Ever		
Severe cognitive impairment	X	Ever		X
End stage renal disease (dialysis, stage 4 or 5)	X	Prior year		
Conditions where measuring BP in the upper arm is contraindicated or difficult			X	
Amputation of the arm	X	Ever	X	
Paralysis of the arms	X	Ever	X	
Lymphedema of the arms			X	
BMI >50	X	Most recent		
Upper arm circumference too small (<22cm) or large (>42 cm)				X

5. Recruitment Methods

We will use existing EHR and administrative data to identify -Kaiser Permanente Washington members aged 18–85, with at least 2 years of enrollment, who at last clinic visit had a high BP ($\geq$138 mm Hg systolic or $\geq$88 mm Hg diastolic) with no history of hypertension diagnosis in the prior 2 years and no antihypertensive medication use in the prior 12 months.

Potentially eligible participants will be mailed a pamphlet about the study along with an invitation letter, a $2 bill and a number to call if they do not want to be contacted. Those not calling will be contacted by phone and screened for eligibility and willingness to participate in the study and those willing to participate will be scheduled to have a screening visit at the Kaiser Permanente clinic they regularly visit or one nearby. Participants will be advised not perform heavy exercise, smoke, or to drink caffeinated beverages for at least 30 minutes prior to their eligibility visit.

At the screening visit the research specialist will ascertain verbal consent to measure BP. S/he will confirm that they have not engaged in heavy exercise, smoked, and not had caffeinated beverages in the prior 30 minutes. S/he will measure their arm, apply the proper sized cuff and measure the participant's BP using the automated clinic BP monitor used by Kaiser Permanente (the validated Omron , 910X BP monitor). As recommended in the US Preventive Services Task Force guidelines, participants will rest for at least 5 minutes before measurement, sit in a chair with back support, with arm supported at heart level, with BP measured 2 times one minute apart*. Participants with BP $\geq$ 140 mm Hg systolic or $\geq$90 mm Hg diastolic at both of the two BP measurements will be eligible to participate. Participants with average BP on two measurements of systolic $\geq$180 or diastolic $\geq$110 mm

Hg BPs will be excluded and offered assistance in getting follow-up care.

*If BP is <140 mm Hg systolic AND <90 mm Hg diastolic at the first BP measurement they are ineligible, and a second BP measurement is not needed. Ineligible individuals will be given $20 to thank them for their time

5.a. Consent Process

The research specialist will obtain oral consent from the participant to take their BP at the screening visit. If the participant's BP is high, the they will be informed that they are eligible for the study and asked if they would like to hear more about it. The research specialist will explain the study in detail, answer questions, and will obtain written informed consent. Individuals who are ineligible at the screening visit will be asked to sign a consent giving us permission to keep their BP measures, collect BP measures and cardio related health data from their EHR, and to re-contact them about future studies.

6. Study Procedures

6.a. Baseline Measurements (Survey 1, Weight 1, Height)

Consented participants will be asked to complete survey 1 (baseline), weight, and height measurement prior to randomization. BP and arm size data will already have been collected as part of screening for eligibility.

6.b. Randomization

We will use a computer-based randomized sequence generator to conceal and randomly assign patients to one of three BP diagnostic groups: (1) Clinic BP; (2) Home BP; or (3) Kiosk BP stratifying by clinic, age group (<60 or >=60), and baseline BP (systolic <or = 150 or 150+ mm Hg). To ensure balance by study arm within strata, group assignments will be block randomized within strata, with block sizes of 3 or 6. Randomization will be concealed to everyone except the study biostatisticians. Randomization sequence will be built into the database, and will not run until BP data, stratification data are entered, and the consent form and the baseline questionnaire are checked as completed.

In order for randomization to occur the following variables need to be entered into the computerized database.

- BP eligibility criteria being met: 2 readings with elevated systolic BP (>=140 mm Hg) OR elevated diastolic BP (>=90 mm Hg) on each measurement.
- BP not too high (average of 2 readings: >=180 systolic, diastolic >=110).
- Data needed for stratification (clinic, age, systolic BP average).
- Consent signed.
- Baseline survey completed.

6.c. Blinding

Because of the nature of the study design, participants and research staff conducting the research group assignment will not be blinded. However, investigators other than the biostatistician will remain blinded until all data collection is complete.

6.d. Interventions

Visit 1 – Completed immediately after screening, consent, and randomization for each diagnostic group. Diagnostic interventions for each group are described below.

Group 1. Clinic BP – Clinic BP diagnosis participants will have their BP rechecked at their primary care clinic:

- Clinic BP participants will be asked to return to clinic to have their BP checked. They will be encouraged to complete this in 2 weeks.
- BP check visits at Kaiser Permanente Washington are generally conducted by medical assistants (MAs) or nurses (collectively referred to as MAs). The clinic medical chiefs prefer that the Clinic BP Group participants schedule the MA BP follow-up appointment. Patients can walk-in to clinic and have a MA BP check without a scheduled visit, but the appointment is preferred. Kaiser Permanente does not charge co-pays for follow-up MA BP visits.
- Clinic BP participants will receive an instruction sheet on BP and getting their BP rechecked.
- Standard protocol at Kaiser Permanente is to use optimal methods for checking BP and repeat the BP a second time if the first BP is elevated. All BPs are recorded in the EHR. Clinic BP participant BPs will be obtained from EHR data.

Group 2. Home BP – Home BP diagnosis participants will check their BP at home:

- Participants will receive a validated, automated Omron N786 home BP monitor with an upper-arm cuff appropriate for their arm size.
- They will receive proficiency training on self-measurement of BP and demonstrate that they can do it on their own. These instructions include no caffeine or exercise prior, resting for five minutes, sitting with their arms, legs, and back supported, applying the cuff correctly to their bared arm (left arm, unless there is a reason for using the alternate arm), arm at heart level.
- They will be instructed to measure their BP twice a day, morning and evening for 5 days. The preferred routine is for the patient to measure their BP first thing in the morning and before they go to bed (when the diurnal pattern of BP is captured, and clothes are less of a problem).
- They will receive an instruction sheet that provides step by step instructions on measuring their BP at home, information about the BP device, and their BP monitoring schedule.
- The study goal is for home BP participants to obtain 20 BP measurements at 5 BP sittings with 2 BPs each time, half in the morning and half in the evening. They will be encouraged to complete this within 2 weeks.
- The Omron 786 monitor has a memory function that holds 100 BP readings which is more than sufficient to capture the number of BP measurements requested during the diagnostic time period. All BP measurements are saved, and the device will not allow users to delete BPs from the memory.
- The home BP monitor will have new batteries, and the research specialist will set the date and time stamp (referred to as the time stamp) for the participants. The batteries will be taped shut, to prevent them from falling out, because if they fall out the time stamp needs to be reset. The time stamp of prior BPs remains intact. However, if not reset, subsequent BPs will be recorded but with no time stamp.
- Participants will be reminded to bring the BP monitor to the research follow-up visit. Once linked by Bluetooth, all BP and pulse measurements, with dates and times will be transferred from the study phone and uploaded to a secure cloud-based site with the patients linked to the patient's study ID (no other identifiers). No data is retained in the study phone. Omron will send weekly Excel file reports of study participant BPs. Omron will not have access to any participant data other than the data listed below and will not collect additional BP data after the BP is downloaded at the research visit.

- Example of BP and pulse data downloaded from one individual's BP monitor

Participant ID 700932			
Date and Time	**Systolic**	**Diastolic**	**Pulse**
6/14/2016 13:59	112	85	87
6/14/2016 13:58	109	86	88
6/14/2016 13:57	154	93	89
6/13/2016 16:46	123	85	76
6/5/2016 22:56	122	89	78
6/5/2016 22:54	131	87	82
Average	**125.2**	**87.5**	**83.3**

Group 3: Kiosk BP – Kiosk BP diagnosis participants will recheck their BPs at a BP kiosk:

- They will receive a smart card to use when taking their BP at the BP kiosk.
- They will be asked to use the validated PharmaSmart BP kiosk installed by the study at their clinic or any of the 60 Bartell Drug stores in the Puget Sound region.
- Participants will receive step by step instruction on taking their BP using the BP kiosk with the smart card and demonstrate that they can do it on their own. These instructions include no caffeine or exercise prior to measurement, resting for 5 minutes, removing bulky clothing (bared or a lightweight top or shirt), inserting their left arm into the kiosk cuff, inserting the smart card into the device, and then taking their BP 3 times consecutively.
- Participants will be asked to return to the kiosk 3 times, for a total of 9 BP measurements. They will be encouraged to complete this within 2 weeks.
- Participants will receive an instruction sheet that provides step by step instructions on measuring their BP using the kiosk and smart card, information about the device, and their BP monitoring schedule. The instructions will remind them to use the BP kiosk with the smart card each time, and if they lose the smart card to call the study for a replacement card.
- PharmaSmart will send weekly de-identified reports of participant BP data with no participant identifiers other than the smart card ID, BP, pulse, time, and date stamp and will have no access to other participant data.

Example of data received from kiosk:

Smart Card GEN-AAC-ZRU:			
Date and Time	**Systolic**	**Diastolic**	**Pulse**
11/26/2014 5:44:00 PM	155	80	68
11/26/2014 5:42:00 PM	155	75	66
11/26/2014 5:37:00 PM	1164	77	65
11/25/2014 6:01:00 PM	145	93	64
11/25/2014 5:59:00 PM	167	81	65
11/25/2014 5:57:00 PM	139	87	64
11/19/2014 12:57:00 PM	156	80	68
Average	**154**	**82**	**66**

At the end of Visit 1: All participants will receive $40 for completing the visit (screening, consent, baseline measures, survey 1, randomization, diagnostic intervention training).

6.e. Visit 2: All 3 BP-CHECK diagnostic groups (Clinic BP, Home BP, and Kiosk BP) will return for a second research visit, approximately 3 weeks after visit 1.

- At this visit they will complete survey 2 and then be fitted for a 24-hour ambulatory BP monitor.
- Home BP arm participants will have their home BPs uploaded into the study computer.
- Clinic, home, and kiosk BP arm participants will all be asked to do a 24-hour Ambulatory BP test.
    - The 24-hour ambulatory BP monitor and cuff will be wiped down and sterilized per organizational Infection Control procedures and new batteries inserted for each individual participant.
    - The computer program will be initialized for the patient and data needed to conduct the test entered.
    - The cuff will be fitted based on arm size.
    - The participant will receive a pamphlet with step by step instructions on 24-hour BP monitor use.
    - They will receive proficiency training on wearing the device, removing it and putting it back on (if needed for showering or driving), and stopping the device.
    - Participants will have their BP checked with the device sitting and standing.
    - They will be asked to return the monitor the next business day (visit 3).
    - The participant will receive $20 for completing the visit

Participants will be able to discuss their clinic, home, and kiosk BPs with their providers as they normally would as part of self-monitoring.

6.f. Visit 3: All participants will be asked to return the 24-hour ambulatory BP monitor the next business day.

- They will be asked to complete survey 3.
- The research specialist will download the 24-hour BP data into the study computer. Average daytime results will be shared with the participant (and whether BP is high defined as a mean daytime average BP $\geq$ 135/85, noting that these are preliminary until reviewed by the physician.
- The patient will receive $30 after they have returned the 24-hour BP monitor and completed the survey.

If the report suggests hypertension, the study physician will check to make sure the provider has opened and read the report. If the provider has not opened the report, the study physician will follow-up with the provider by secure messaging or phone. Providers will follow normal protocols in their response to each patient's 24-hour report. The reports will include the study physician's contact information and they will be able to contact them if they have questions about interpretation of the results. On the Participant 24-Hour Report, we will recommend the participant contact their provider if the report shows that they have hypertension.

6.g. Visit 4: All participants will be asked to return approximately 6 months after randomization. The participant will:

- Have their BP measured 2 times using the same procedure as the screening visit.
- Have their weight measured.
- Complete survey number 4.
- Be asked about any adverse events such as hospitalizations.
- Receive $30 for completing the visit.

6.h. Procedures for participants opting out of research visits, surveys, and tests.

Participation in this study is voluntary. Even after consent, participants may choose to not do specific study components (such as wearing the 24-hour BP monitor), decline survey questions, or choose not attend study visits. Participants will not be considered withdrawn from the study unless they state clearly that they wish to withdraw. If they take back their consent, we may still use information collected before withdrawal, but will not collect any additional information and will destroy any record of their name or other information that may identify them.

7. Qualitative Assessments

Participant Interviews: To provide rich descriptive data on patient experiences with the different diagnostic testing methods, qualitative data will be collected through participant interviews from three study clinics (recruitment sites) with the goal of interviewing 12 patients per clinic evenly distributed across the three arms of the study and participants with baseline systolic BP $\geq$ 150 mmHg versus 140 to <150 mmHg. We will conduct in-person interviews with the same individuals at two time points, once shortly after Visit 3 when they received their 24-hour BP report and again approximately 6 months later, shortly after their Visit 4 (6-month follow-up visit). The purpose of the interviews will be to collect detailed information on participant experiences with testing; comfort carrying out the test; changes to daily routines and behaviors due to diagnostic testing; and impact of the testing on stress, anxiety and concern about health, and interactions with healthcare teams. We will also explore participant understanding of results they are given and their meaning, what they need to do next, and what, if any, shared decision making has occurred with healthcare teams.

To facilitate analysis, interviews will be recorded. Atlas.ti software will be used to manage and code the data.[8,9]

8. Outcomes:

Aim 1: To assess the comparability and accuracy of clinic, home, and kiosk BP to daytime 24-hour ambulatory BP (the reference standard) for making a new diagnosis of hypertension. Systolic (primary) and diastolic (secondary) blood pressure outcome measures will be the average of all respective measures as defined by randomization arm as follows:

1) Clinic BPs will include all ambulatory outpatient BPs taken between visit 1 and visit 2 and recorded in the EHR. This includes primary and specialty care visits, but not emergency or hospital BPs. 2) Home BPs will include all BPs collected on the home BP monitor and obtained between visit 1 and 2, except for the 2 training BPs that occur during visit 1. 3) Kiosk BPs will include all kiosk BPs transmitted via the Smart Card and obtained between visit 1 and 2, except for the 3 training BPs that occur at visit 1.

24-hour ambulatory BP outcomes for all randomization groups will include all daytime BPs collected during 24-hour monitoring, except for the 2 BPs taken by the research specialist at visit 2 to assure that the cuff and monitor are performing properly. Daytime systolic and diastolic BPs are averaged. Nighttime BPs are obtained, as this is a standard part of 24-hour ambulatory testing and provides additional data, but this and other data captured (e.g., nocturnal dipping, morning surge) will not be used for the primary or secondary outcome assessments.

Aim 2: To compare the acceptability of clinic, home, kiosk, and 24-hour ambulatory hypertension diagnostic testing. Outcomes are defined as percent of patients who adhere to their assigned diagnostic regimen and the acceptability of the BP measurement methods (e.g., patient-reported outcomes).

Adherence will be measured as the percent of participants who complete their assigned BP testing protocol from the time of randomization to visit 2. Adherence will be defined by randomization arm as follows: 1). Clinic –EHR evidence of at least one clinic visit with a BP measurement; 2) Home – completion of at least 16 of the 20 home BP measurements including measurements on 4 or more separate days; 3) Kiosk – completion of at least 6 of the 9 kiosk BP measurements with measurements on 2 or more separate days. Adherence to 24-hour ambulatory testing will be defined as at least 14 daytime 24-hour ambulatory measurements[10,11] BP measurements done as part of the research visits or patient training will not be included in diagnostic accuracy and adherence assessments.

Patient-reported measures of acceptability of the BP diagnostic tests will be assessed four times: at visit 1 (baseline before randomization); at visit 2 (specific to their assigned group – Clinic, Home, or Kiosk BPs), approximately 3 weeks after randomization and after diagnostic testing according to randomized assignment; at visit 3, 1 day later, after completion of 24-hour ambulatory testing; and at 6 months (Table 2). Acceptability of diagnostic tests will include the 13-items questionnaire used by Little et al.,[12] to assess: (1) ease and ability to do the test (e.g., easy to do, wait time); (2) perception of accuracy; and (3) disturbance, discomfort, and social acceptability (e.g., made me anxious, disturbs activities or work, embarrassment). Each item will be answered using a 7-point Likert scale ranging from strongly agree to strongly disagree, with a lower composite score indicating higher acceptability of the diagnostic test.

Aim 3: To compare patient-reported and BP outcomes 6-months after randomization by randomization group and by whether hypertension was diagnosed. Longer-term patient-reported outcomes will include: worry about high blood pressure, heart attack, and stroke using a measure developed by McClure et al. to assess patients' perceptions of their lifetime risk of stroke, risk compared to others, and potential impact[13]; health related quality of life using the Patient Reported Outcomes Measurement Information System (PROMIS) measure of general physical and mental health (Global Health [GH10])[14]; and change in lifestyle behaviors, including questions on fruit and vegetable intake[15] physical activity[16] and salt intake.[17]

BP outcomes at 6-months will include receipt of a new hypertension diagnosis (based on a new ICD 10 diagnosis in the EHR; I-11, I-12, or 1-13); and systolic, diastolic, and BP control at 6-months (systolic BP of <140 mm Hg and diastolic BP < 90 mm Hg based on the average of 2 BPs at the 6-month research visit

Aim 4: To examine provider knowledge, preferences, and beliefs about BP diagnostic tests. To assess provider (physicians, nurses, medical assistants) knowledge, attitudes and beliefs, we will collect surveys at the start of clinic participation in the study. Questions will include knowledge, use, and beliefs about clinic, home, kiosk, and 24-hour ambulatory BP for making a new diagnosis of hypertension as well as their familiarity with the USPSTF and ACC/AHA hypertension diagnosis guidelines. We will also perform in-depth interviews with approximately 30 physicians following clinic participation, to provide rich information on their experience with the different methods for confirming high BP, making a hypertension diagnosis, and interacting with patients about their new diagnosis. We will focus this sample on physicians who had patients that participated in the study and received at least one 24-hour ambulatory BP report, to learn more about their experience of receiving hypertension diagnostic results.

Table 1: BP-Check Aims and Outcomes		
Aim	**Outcomes**	**Timing of data collection**
Aim 1 Comparative performance of clinic, home, and kiosk BPs compared to daytime ABPM (primary outcome)		
Clinic BP Arm Home BP Arm Kiosk BP Arm Compared to	Average SBP and DBP at outpatient visits (EHR data) Average SBP and DBP of measures collected on the home monitor Average SBP and DBP of measures collected via Smart Card at the kiosk ABPM (average daytime SBP and DBP) all 3 arms	Between visit 1 and visit 2 " " Between visit 2 and visit 3
Aim 2 Adherence to clinic, home, kiosk BP and ABPM regimens (primary outcome)		
Clinic BP Arm Home BP Arm Kiosk BP Arm All 3 arms	At least one outpatient encounter with at least 1 BP At least 16 of 20 (protocol) BPs on at least 4 separate days At least 6 of 9 (protocol) BPs on at least 2 separate days At least 14 daytime BP measurements during the 24-hour testing period	Between visit 1 and visit 2 " " Between visit 2 and visit 3
Aim 2 Acceptability of clinic, home, kiosk BP and ABPM regimens		
All 3 arms	Self-reported acceptability of different BP methods Qualitative acceptability data from patient interviews	Visit 1, 2, 3 and 4 After visit 3 and 4
Aim 3 6-month BP and patient-reported outcomes		
All 3 arms	% with controlled BP (SBP< 140 or DBP < 90 mm) Change in SBP and DBP % with mean daytime ABPM SBP $\geq$ 135 or DBP $\geq$ 85 mm Hg and hypertension diagnosed Self-reported acceptability of BP diagnostic methods Self-reported lifestyle changes (e.g. salt intake see Table 2) Self-reported health related quality of life Self-reported worry and anxiety about high BP, stroke, heart attack Qualitative data on patient-reported outcomes from patient interviews	Visit 4 (average of 2 research BPs) Between visit 1 and visit 4 EHR between visit 3 and 4 Visit 4 questionnaire Change between visit 1 and visit 4 Change between visit 1 and 4 Change between visit 1, 2, 3, and 4 After visit 3 and 4
Aim 4 Provider knowledge, attitudes, and beliefs BP diagnostic methods		
Medical assistants, nurses, physician assistants, physicians Physicians only	Baseline provider knowledge, attitudes and beliefs Qualitative data on physician knowledge, attitudes and beliefs from physician interviews	Provider survey at baseline After patients complete ABPM
Abbreviations; BP, blood pressure; SBP, systolic BP; DBP, diastolic BP; ABPM, 24-hour ambulatory BP; HER, electronic health record		

9. Data Analysis

Aim 1: For the primary analysis, we will estimate mean difference between each diagnostic BP group and the 24-hour BP (how different is the diagnostic BP from the reference standard?). We will use a linear regression model to estimate the mean difference in systolic BP between the diagnostic and the 24-hour reference standard test. The dependent variable will be the within person difference (diagnostic BP – 24-hour reference standard). Regression models will include indicator variables for randomization group and adjust for age and sex as well as other baseline characteristics that are imbalanced by intervention group or related to the outcome (α level of .10). We will use generalized estimating

equations (GEEs) with robust standard error estimation to fit these models to relax the assumption of outcome normality.

For inclusion in the primary analysis, participants must complete at least one clinic, home, or kiosk BP measurement after the baseline visit and 24-hour ambulatory BP measurements (the reference standard). Daytime 24-hour ambulatory BP will be defined as BPs collected between 7AM and 11PM, with a minimum of 14 daytime BP measurements required for inclusion in primary analyses. Participants with missing outcome data (who did not complete one or both tests) may be different from participants completing testing. Our primary analysis will use a complete-case approach, which will yield unbiased results if the primary outcome is missing at random given the adjustment for baseline characteristics imbalanced between groups. However, if data are not missing at random the adjusted complete-case approach may be biased. Therefore, we will conduct sensitivity analyses to account for missing data. We will assess differences in patient characteristics between those completing and not completing BP testing, and consider propensity weighted regression models to address potential bias due to differential missing data. We will fit a logistic regression model to estimate the probability of completing BP testing, accounting for the BP measure from the study baseline visit and other characteristics related to testing completion. Analysis will be weighted using the inverse of these estimated probabilities, and analysis results will be generalizable to the randomized population rather than the subset that completed testing. We will conduct a sensitivity analysis defining the diagnostic BP outcome based on pre-specified definitions of adherence to their diagnostic group measurement protocols, a minimum of 1 clinic BP, 16 home BPs (over at least 4 days), and 6 kiosk BPs (over at least 2 days) during the 3-week diagnostic time period. This analysis will determine whether the study results depend on adherence to the diagnostic protocol. Analysis of the difference in diastolic BP between diagnostic and 24-hour BP will use the same methods as described for systolic BP.

We will explore heterogeneity of diagnostic accuracy to determine if the relative accuracy of clinic, home, and kiosk BP varies by patient characteristics including age, sex, race/ethnicity, baseline BP, and BMI. We will include interaction terms between randomization group and these characteristics to test if diagnostic accuracy differs by subgroup. Secondary outcome analysis will follow a similar approach. To estimate sensitivity, we will fit a logistic regression analysis using a GEE model with robust error estimation. The outcome variable is binary, indicating whether clinic, home, or kiosk BP was above the threshold for hypertension, and the model is fit using the subgroup with hypertension according to 24-hour BP. To estimate specificity, the outcome variable indicates if the diagnostic test BP was below the threshold for hypertension (tested negative), and the model is fit using the subgroup without hypertension according to 24-hour BP. The thresholds for hypertension yes/no will be based on guideline established standards, with clinic as either average diastolic BP >=90 mm Hg or average systolic BP >=140 mm Hg, home BP average diastolic BP >=85 mm Hg or average systolic BP >=135, kiosk BP average diastolic BP >=85 mm Hg or average systolic BP >=135 mmHg (standards are not established, so we will perform sensitivity analyses varying the thresholds for each group), and 24-hour BP average daytime diastolic BP >=85 mm Hg or average daytime systolic BP >=135 mmHg.

Aim 2: To compare the acceptability of clinic, home, kiosk, and 24-hour ambulatory BP hypertension diagnostic testing. Outcomes are defined as the percent of patients who adhered to their assigned diagnostic regimen and the acceptability of the BP measurement methods (e.g., patient-reported outcomes). Adherence is be a binary outcome defined specifically by diagnostic arm: Clinic, completion of at least one follow-up BP measure; Home, at least 16 measures, with measures on 4 or more different days; and Kiosk, at least 6 measures, with measures on at least 2 different days. Adherence to 24-hour ambulatory BP testing is defined as at least 14 daytime 24-hour ambulatory measurements. To compare the proportion completing each diagnostic test to the proportion completing 24-hour ambulatory BP we will fit a GEE model with log link function, and binomial error distribution, and robust standard error estimation, to directly estimate the relative risk in proportions completing each testing

protocol. The dependent variable is adherence to the protocol (yes/no), and the independent variables are indicator variables of each protocol type (clinic, home, or kiosk).

Analysis of secondary outcomes of acceptability (ease of testing, perception of accuracy, discomfort) will follow a similar approach. For continuous measures of self-reported measurement acceptability, we will use linear regression models fit with GEEs to estimate differences in mean acceptability by measurement method (home, clinic, kiosk and 24-hour ambulatory). We will use interaction terms to test whether differences in test acceptability (both primary and secondary outcomes) vary by patient characteristics (baseline BP, age, sex, race/ethnicity, BMI, education).

Aim 3: To compare patient-reported and BP outcomes at 6 months by randomization group, we will fit a separate GEE model for each outcome, using link function and error distribution appropriate for the type of outcome. For continuous outcomes, such as systolic and diastolic blood pressure, measures of anxiety, and healthy related quality of life, we will use a generalized linear model with identity link and Gaussian error distribution. The dependent variable is the change in outcome between baseline and 6-months, and indicators for randomization group were the independent variables. Models adjusted for the baseline value of the outcome, age, sex, BMI, and baseline systolic and diastolic BP. For binary outcomes, such as controlled BP, or reporting regular physical activity, regression models will use a log link and binomial errors to estimate the relative risk of the outcome in the Home or Kiosk group, relative to the Clinic group. All models will use robust error estimation.

In exploratory analyses, we will use similar analytic methods to assess whether BP outcomes at 6-months differed by whether or not a new hypertension diagnosis was recorded in the EHR between randomization and the 6-month visit. Exploratory analyses will be limited to the subset of participants who had hypertension, based on study measurement of mean daytime 24-hour ambulatory BP (≥135 mm Hg systolic or ≥ 85 mm Hg diastolic).

To address bias due to missing outcome data for Aims 1-3, we will adjust for pre-specified baseline (age, sex, BMI, and baseline BP) and imbalanced (e.g., education) covariates by randomization group. For Aim 1 primary outcomes, we will conduct sensitivity analyses using inverse probability of treatment weighting adjusted for any baseline covariates that showed imbalance by randomization group.

Aim 4: Analyses of responses to the provider survey will be primarily descriptive. Summary statistics will describe provider knowledge; preferences and beliefs about BP diagnostic tests before the study, including knowledge of the USPSTF hypertension guidelines for diagnosing hypertension; and if aware of the guidelines, the degree to which the provider felt the guidelines were appropriate, acceptable, and feasible to implement.

Qualitative analyses: We will code interview transcripts for patients and providers using both *a priori* and emergent concepts.[18] Coding will be informed by a phenomenological approach[19-21] to explore the experiential aspects of BP testing for both patients and providers. The code list and codebook will be developed iteratively by first reviewing transcripts and drafting separate code lists for the patient and provider interviews. The qualitative analysis team will then conduct successive rounds of coding comparisons between at least two coders until they are no longer adding new codes to the code list and have achieved a shared understanding of the code definitions and how to apply the codes (as evidenced by a high level of agreement between coders when coding independently and then comparing codes). Once this shared understanding of the codebook is achieved, transcripts will be coded independently by a single coder. After all transcripts are coded and entered into Atlas.ti,[8,22-24] (qualitative data management software), the data will be organized by code and reviewed again for themes and subthemes. Coding memos will be drafted to summarize the findings and provide supporting evidence.

10. Statistical power:

With a sample size of 510 (170 per group) and assuming a protocol completion rate of at least 80%, evaluation of test accuracy will be based on a sample size of 136 for each group. We have 80% power to detect a 4.1 mm Hg difference in systolic BP accuracy between any two groups (assuming a standard deviation of 12.1 mm Hg for the paired difference in BP measures).[25] For example, a statistically significant result would be home BP underestimating systolic BP by 2.6 mm Hg and kiosk BP overestimating systolic BP by 2.1 mm Hg compared to 24-hour BP difference between group means is 2.1-(-2.6)=4.7, which is larger than the minimum detectable difference of 4.1. We have 80% power to detect a 2.8 mm Hg difference in diastolic BP accuracy between any two groups (assuming a standard deviation of 8.3 mm Hg). Therefore, we have good power to make all primary comparisons of interest.

Assuming an 80% follow-up rate for the participant surveys, the minimum detectable standardized effect (Cohen's d) for differences between randomization groups for the change in patient-reported outcomes is 0.34. This means that if the true group means differ by more than 0.34 of a standard deviation, our sample size has 80% power to detect a statistically significant result. This effect size is considered moderate and reflects a meaningful difference in patient outcomes. Estimation of least detectable differences assume 80% power, and a 0.05 type 1 error rate.

Provider survey: We expect that provider surveys will be completed by 60% of staff,[26] providing us with at least 100 responses to each questionnaire. Analyses of responses will be primarily descriptive, with summary statistics describing provider knowledge, preferences and beliefs about BP diagnostic tests before and after the study, including their knowledge of the USPSTF hypertension guidelines for diagnosing hypertension and if they are aware of the guidelines to what degree the feel they are appropriate, acceptable, and feasible to implement.

11. Protocol Amendments

Our original plan was to require potential participants to have a systolic BP $\geq$ 140 mmHg or a diastolic BP $\geq$ 90 mmHg at their last out-patient clinic visit. While identifying our potential study sample, we observed that we could increase our sample by almost 50% if we decreased BP eligibility slightly, to a systolic BP $\geq$ 138 mmHg or a diastolic BP $\geq$ 88 mmHg. We suspect this large difference was due, to organizational emphasis on BP control $\leq$ 140/90 for individuals with or without a hypertension diagnosis, and additional measurements and visits required if BP was $\geq$ 140/90. This change was approved by the KPWA IRB.

12. Data Collection

Assess data source adequacy. Data sources will include biometric data obtained at research visits; data from the EHR, diagnostic tests, and participant. Biometric data obtained at research visits includes upper arm circumference, device type and ID, systolic BP, diastolic, BP, pulse, weight and visit 1 and 4, height at visit 1, and the date and time of each measurement. EHR BPs will be captured at clinic visits, except for the eligibility screening visit, where we will simulate best practices at Kaiser Permanente Washington, which is to recheck BP if the initial BP is high. Similar to the organization, for study eligibility, we required both the first and second BP to be high. Additional data captured from the EHR will include patient phenotype data (see table), anti-hypertensive medications utilization after randomization (patients on antihypertensive medications prior to randomization are excluded), and utilization of primary, specialty, and urgent care, hospitalizations, and procedures related to BP and hypertension care (such as 24-hour BP diagnostic tests not performed by the study). De-identified BP and heart rate data for each BP measurement (monitor ID, date, time, systolic BP, diastolic BP) will be transferred to the research database by: (1) home BP monitor data via Bluetooth connectivity to the research computer at research visit 2; (2) kiosk BP through HIPPA compliant, secure transfer from PharmaSmart computer servers and uploaded into the research database between visit 1 and 2; and

(3) 24-hour BP through a USB connection to the research computer at visit 3. Participant-reported data will be captured using patient self-administered surveys directly into the research computer (tablet) and database (with the research specialist assisting if needed) and will include demographic data (survey 1 and 2), patient-reported outcomes (survey 2, 3, and 4). Surveys will include automatic range checks and appropriate skip patterns for branching questions.

Data disposition. We will retain a de-identified database of the study sample (age, sex, race/ethnicity/insurance type) to determine the representativeness of individuals agreeing to a screening visit and those not. Identifiers used to contact patients will be destroyed after study recruitment is completed.

Individuals attending a study screening visit will be asked to give verbal consent to check their BP. Individuals who are eligible will be asked to sign informed consent to participate in the study, with permission to collect and keep study data and electronic health record data (BPs, hypertension, CVD risk factors, and CVD events including stroke and myocardial infarction, medications for hypertension, hypertension related laboratory tests and procedures, and clinic, urgent care, specialty visit, hospital visits). We will collect and keep consented and enrolled participants data until December 31, 2029. All study participants will contribute data to study analyses, unless they provide a request to withdraw their consent and previously collected data.

Individuals who are ineligible will be asked to sign an informed consent giving their permission for us to retain their BP and to collect CVD health and utilization related EHR data (BPs, hypertension, CVD risk factors, and CVD events including stroke and myocardial infarction, medications for hypertension, hypertension related laboratory tests and procedures, and clinic, urgent care, specialty visit, hospital visits) until December 31, 2029 for secondary analyses or future study participation. We will also ask for permission to re-contact if needed.

13. Privacy, Confidentiality, and Data Security

All persons handling study data are Kaiser Permanente Washington Health Research Institute employees, who have signed a Confidentiality Statement that stipulates that any violation of confidentiality is grounds for termination of employment. Only persons directly involved in the study will have access to data. All data will be stored on password-protected computers which only staff involved with this study can access. Identifying information will be stored in separate files that are password protected and only study team members who need to know will have the password (e.g. study RS who does recruitment).

BP device vendors will not receive any patient identifiers. We will obtain BPs from home BP and kiosk BP devices through unique identifiers that will only be linkable to study participants by study team programmers for linkages to the study database within the Kaiser Permanente firewall in password protected databases. Any data that is shared outside of Kaiser Permanente will be de-identified with no patient identifiers or small cells of data released.

To protect confidentiality, we will assign a unique study number to individual participants. This study number will be used on study documents rather than subjects' names. We will maintain and protect a linking file which links study number to participant's names and other direct identifying information. This file will be kept in locked, password protected computers at Kaiser Permanente Washington Health Research Institute. Identifiers will be destroyed no later than December 31, 2029.

14. Data Sharing

A deidentified data set and data dictionary may be requested by writing to the primary investigator at Bev.B.Green@kp.org

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

This study will have a Data Safety Monitoring Board (DSMB) to ensure safety of research participants. The DSMB will include an external researcher with prior DSMB experience (the chair), a clinician, and a patient. They will meet once in the first 6 months after study funding and prior to patient enrollment to review study protocols and plans for study reports (enrollment, completion, and adverse event-reporting tables by study group) and recommend changes. The study team will track participant-reported serious adverse events whether related or not to study participation. The team will provide ongoing reports to the DSMB and IRB. The DSMB will meet twice per year, in person or by phone, as directed by the committee. The study Principal Investigator, biostatisticians, and project manager will attend all DSMB meetings.

The DSMB will receive ongoing reports to ensure data validity and integrity, including recruitment reports, participant characteristics by study arm to ensure adequacy of randomization, participant completion of study visits, and completeness of study data collection. The DSMB may also choose to see outcome data, with this data blinded except to the study biostatisticians, the DSMB, and if the DSMB deems necessary the study Principal Investigator.

16. Risks and Benefits

a. Risks to Subjects

Potential risks include discomfort at answering questions or psychological distress due to research procedures, breach of confidentiality, and physical discomfort from having BP measured and other minor adverse events such as skin irritation. Also, participants may experience psychological distress from being told BP is high or being given a new diagnosis of hypertension.

We will investigate any reports of adverse events made known to the study team by patient self-report during study visits or by clinic personnel. At study visits 2 and 4 they will be asked if they experienced any new and serious health problems that resulted in an emergency room visit or hospitalization. We will investigate health problems that are potentially serious adverse events or related to study participation.

b. Potential Benefits to Subjects

Participants may experience improvement in their physical health due to having their blood pressure measured, receiving advice to have follow-up, and coordination of care for very high BPs.

17. Costs to Participants

Participants will incur transportation costs in order to attend their clinic visits. There will be no cost for the 24-hour BP monitoring.

18. Compensation to Participants

A $2.00 bill will be included in every invitation letter as a way to increase recruitment rates. Participants who come to the clinic for a screening visit and complete a BP measurement will be given $20.00. Participants who are eligible and enroll in the study will receive an additional $20.00 at the end of Visit 1. All enrolled participants will receive $20 for the completion of Visit 2, $30 for the completion of Visit 3 (24-hour BP data collection) and $30 for completing the protocol.

SUBJECT PAYMENTS	Clinic BP	Home BP	Kiosk BP
Recruitment Letter	$2.00	$2.00	$2.00
Screening Clinic Visit for eligibility	$20.00	$20.00	$20.00
Clinic Visit (1) - baseline	$20.00	$20.00	$20.00
Clinic Visit (2) - 24hr monitor	$20.00	$20.00	$20.00
Clinic Visit (3) - return 24hr monitor	$30.00	$30.00	$30.00
Clinic Visit (4) – 6-month f/up	$30.00	$30.00	$30.00
Total	$122.00	$122.00	$122.00

Participants randomized to Home BP will receive a home BP monitor at Visit 1. We will also give home BP monitors to the Clinic BP and Kiosk BP groups at their 6-month visits.

Smart cards that can be used at Bartell Drugs kiosks will be given to Kiosk BP group at Visit 1. Smart cards will be given to Clinic BP and Home BP groups at their 6-month visits.

Patients and physicians who participate in qualitative interviews will receive $50 for each interview completed, a total of $100 for participants who complete two interviews, and $50 for the single interview requested for physicians.

All providers (physicians, nurses, medical assistants) who complete the web-based provider survey will be entered into a drawing to receive $100 Amazon gift certificate. One winner will be drawn for every 20 respondents from each clinic.

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