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Blood Pressure Checks and Diagnosing Hypertension (BP-CHECK): Design and Methods of a Randomized Controlled Diagnostic Study Comparing Clinic, Home, Kiosk, and 24-Hour Ambulatory BP Monitoring

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Abstract

Background: The US Preventive Services Task Force recommends out-of-office blood pressure (BPs) before making a new diagnosis of hypertension, using 24-hour ambulatory (ABPM) or home BP monitoring (HBPM), however this is not common in routine clinical practice. Blood Pressure Checks and Diagnosing Hypertension (BP-CHECK) is a randomized controlled diagnostic study assessing the comparability and acceptability of clinic, home, and kiosk-based BP monitoring to ABPM for diagnosing hypertension. Stakeholders including patients, providers, policy makers, and researchers informed the study design and protocols.

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Human Subjects:

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Conflict of interest:

Dr. Green, Ms. Anderson, Dr. Cook, Ms. Ehrlich, Dr. Hsu, Dr. McClure, Dr. Munson have no conflicts of interest to report
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Methods: Adults aged 18–85 without diagnosed hypertension and on no hypertension medication with elevated BPs in clinic and at the baseline research visit are randomized to one of 3 regimens for diagnosing hypertension: (1) clinic BPs, (2) home BPs, or (3) kiosk BPs; all participants subsequently complete ABPM. The primary outcomes are the comparability (with daytime ABPM mean systolic and diastolic BP as the reference standard) and acceptability (e.g., adherence to, patient-reported outcomes) of each method compared to ABPM. Longer-term outcomes are assessed at 6-months including: patient-reported outcomes, primary care providers' diagnosis of hypertension; and BP control. We report challenges experienced and our response to these.

Results: Enrollment began in May of 2017 with a target of randomizing 510 participants. BP thresholds for diagnosing hypertension in the US changed after the trial started. We discuss the stakeholder process used to assess and respond to these changes.

Conclusion and Public Health Impact: BP-CHECK will inform which hypertension diagnostic methods are most accurate, acceptable, and feasible to implement in primary care.

Keywords

Blood pressure; Blood pressure monitoring; Hypertension; Randomized controlled trial; Patient reported outcomes; Primary care

Background

Hypertension is the leading risk factor for cardiovascular disease (CVD), the most common cause of avoidable death and disability in the U.S.^{1, 2} Substantial evidence supports that early identification and control of hypertension reduces CVD events and death.^{3, 4}

Hypertension is the most common diagnosis at clinic visits and accounts for over half of diagnoses in adults with chronic conditions.⁵ While the majority of adults with hypertension are on treatment, more than 1 in 3 adults with hypertension may be unaware they have high BP.⁶ Wall et al. noted that up to 30% of clinic patients with sustained high BP “hide in plain sight” with multiple documented elevated BP measurements, but have no hypertension diagnosis and are not on antihypertensive medications.⁷

The US Preventive Service Task Force (USPSTF) recommends screening all adults aged 18 years or older for hypertension (“A” recommendation, strong evidence of benefit).^{8, 9} For patients with high screening BP in clinic, the USPSTF recommends follow-up BP testing outside the clinic, preferably 24-hour ambulatory BP monitoring (ABPM) or home BP measurements. ABPM uses a full upper-arm cuff connected to a waist-carried device that is worn continuously and inflates every 20 to 30 minutes during the day and every 30 to 60 minutes at night.¹⁰ Hypertension diagnosis is based on average BP during the day or over 24 hours. Average BP readings from measurements over multiple days using a home BP monitor (HBPM) is also endorsed as a method for confirming the diagnosis of hypertension. Similarly, the American College of Cardiologists and American Heart Association sponsored hypertension guidelines (ACC/AHA) recommends out of office BP monitoring by ABPM or HBPM before diagnosing hypertension.¹¹

The USPSTF, ACC/AHA recommendations are intended to prevent misdiagnosis of hypertension. In studies reviewed by the USPSTF, 5–65% of patients with high BP in clinic have “white coat hypertension” with normal ABPM or HBPM BPs on average outside of clinic. The USPSTF review noted that patients with white coat hypertension had similar long-term risk for CVD events and death to individuals without hypertension, although follow-up for incident hypertension was recommended.^{9, 12} Other international organizations and societies also endorse ABPM, or alternatively HBPM, before making a new diagnosis of hypertension, and recommend specific diagnostic protocols (Appendix).

Confirming new hypertension diagnoses with ABPM or HBPM could reduce over-diagnoses and harms such as unnecessary treatments, adverse treatment effects, and mislabeling patients with a chronic condition. However, ABPM may not be readily available in the community. Clinicians may use HBPM, but do not always follow recommended guidelines.^{13, 14} Patients might find ABPM cumbersome, or may not be able to or want to purchase a home BP monitor. Kiosk BP checks at a nearby pharmacy could be a convenient way to assess BP outside of clinic visits. Blood Pressure Checks and Diagnosing Hypertension (BP-CHECK) is a randomized controlled diagnostic study that will provide new knowledge on accuracy and patient-acceptability of methods for diagnosing hypertension.

The study aims are as follows:

Aim 1: To assess the comparability and accuracy of clinic, home, and kiosk BP to daytime ABPM (the reference standard) for making a new diagnosis of hypertension. We hypothesize that compared to the reference standard (daytime ABPM), home BP and kiosk BP will be more comparable than clinic BP.

Aim 2: To compare adherence to and the acceptability of clinic, home, kiosk, and ABPM hypertension diagnostic testing. We hypothesize that patients will prefer clinic, home, or kiosk BP measurements compared to ABPM, however preference may differ depending on concordance with ABPM result.

Aim 3: To compare patient-reported outcomes (e.g., anxiety, health-related quality of life, and behavior change) and BP outcomes 6-months after the diagnostic period by randomization group and by whether hypertension was confirmed or not based on daytime ABPM testing result.

Aim 4: To examine provider knowledge, preferences, and beliefs about BP diagnostic tests pre- and post-study; to identify implementation barriers and facilitators for clinic, home, kiosk, and ambulatory BP monitoring.

Methods

Overview

Blood Pressure Checks for Diagnosing Hypertension (BP-CHECK) is identifying patients aged 18–85 with high BP at their most recent clinic visit who do not have a diagnosis of and are not receiving medications for hypertension. Individuals meeting these inclusions are invited to a screening visit. Patients with high BP at the screening visit are randomized (target 510 patients) and assigned to (1) Clinic BP, (2) Home BP, or (3) Kiosk BP diagnostic

groups for confirming a new diagnosis of hypertension (Figure 1). The clinic BP group is asked to return to clinic to have their BP rechecked. The Home BP group is asked to measure their BP, twice a day, with two measurements each time, for 5 days (4 measurements per day for 5 days). The Kiosk BP group is asked to measure their BP three times on 3 separate days using a BP kiosk at their clinic or a nearby pharmacy. Clinic, Home, and Kiosk group participants complete their diagnostic protocols over approximately 3 weeks after which all participants are asked to complete ABPM. Participants complete surveys at baseline prior to randomization (Visit 1), after completing clinic, home, or kiosk BPs (Visit 2), after ABPM (Visit 3), and at 6 months (Visit 4).

BP-CHECK's study design and implementation is informed by stakeholders including Patient and Stakeholder Advisory Committees (PAC and STAC), and two patients who serve as key personnel and investigators on the study team. BP-CHECK also has a Data and Safety Monitoring Board (DSMB) that meets biannually to review study conduct and adverse events. The formal protocol presented here was reviewed and approved by our Patient and Stakeholder Advisory Committees, the DSMB, our institutional review board, and submitted to the Patient Centered Outcomes Research Institute (funder) and is registered with [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03130257) (NCT03130257).

BP-CHECK focuses on patient-centered outcomes and the downstream consequences of diagnostic testing on longer-term patient psychological, behavioral, social, and physical outcomes (e.g., well-being, healthy lifestyles, and BP at 6 months). The assessment design, which includes surveys of medical staff and in-depth interviews with both patients and providers, is grounded in the Social Ecological Model^{15, 16} (Figure 2). This framework highlights how a diagnosis of hypertension and the acceptability and accuracy of different diagnostic techniques are influenced by factors ranging from the individual level all the way up to the policy level. For example, individual knowledge, skills, and attitudes may be affected by an individual's comfort with different methods for measuring BP and the reactions of family and friends. At the level of the healthcare organization, established customs and practices and decisions about how best to allocate resources influence decisions for adopting new technologies and diagnostic practices. Community and policy standards affect diagnostic practice through reimbursement policies, incentives, and regional and national practice norms.

Setting

The study setting is Kaiser Permanente Washington (KPWA), an integrated health care system that provides health insurance coverage and/or health care to approximately 700,000 patients in Washington State. Most patients have either employment-based or government sponsored insurance (e.g., Medicare). The study screening visits and follow-up research visits are conducted at the patient's regular or a nearby clinic, making it more convenient for patients to participate and our results more applicable to "real-world" practice, as hypertension is usually diagnosed at clinic visits in current practice.

KPWA has specific guidelines for diagnosing and treating hypertension. KPWA guidelines for treatment targets were changed in response to the updated ACC/AHA hypertension guidelines (November 2017)¹¹ with systolic targets for BP control in individuals aged 60

and over lowered from <150 mmHg to <140 mmHg (JNC 8).¹⁷ KPWA also subsequently endorsed (April 2018) systolic BP targets of < 130 mmHg for select individuals age 50 and over with CVD or a 10-year risk of CVD or at least 10%. However, KPWA and Kaiser Permanente overall did not change the threshold for diagnosing hypertension to > 130 mmHg systolic or > 80 mmHg diastolic, as recommended by the updated ACC/AHA guidelines. In day to day practice elevated BP is still defined at KPWA as a clinic BP of 140 mmHg systolic or 90 mmHg diastolic in clinic, or daytime average ABPM mean BP of 135 mmHg systolic or 85 mmHg diastolic. Adults have their BP measured at almost all clinic visits and if BP is elevated (> 140 systolic or > 90 diastolic) on both an initial and repeated measurement, are asked to return for follow-up measurements.

Eligibility

Electronic health record (EHR) data are used to identify KPWA members aged 18–85 who at their last clinic visit had a high or borderline high BP (> 138 mmHg systolic or > 88 mmHg diastolic) with no history of a hypertension diagnosis in the prior 2 years and no antihypertensive medication use in the prior 12 months. EHR data are also used to exclude patients who have: very high BPs (systolic >180 mmHg or diastolic >110 mmHg) at this prior visit; severe life-limiting illness (e.g., hospice, Alzheimer's disease); atrial fibrillation and other significant arrhythmias (e.g., pacemaker use) for whom automated device BP measurements may not be as accurate; patients with end-stage renal disease or who require dialysis (as BP management differs substantially for this population); a diagnosis of psychosis (as they may not be able to complete study procedures); and conditions such as amputation, paraplegia, lymphedema, or brachial shunts that render measurement of BP at home or with a BP kiosk difficult. Children under age 18 and pregnant women are excluded as recommendations for a diagnosis of high BP for these groups differ.

Recruitment

Potentially eligible patients are mailed an invitation letter and a pamphlet about the study along with a \$2 bill and a number to call if they do not want to be contacted. Including a \$2 bill has been shown to increase study enrollment rates.¹⁸ Invited patients are contacted by phone and screened for eligibility (e.g., not pregnant, no hypertension medications). Those willing to participate are scheduled for a screening visit at their regular or a nearby KPWA clinic.

At the screening visit, the research specialist confirms that the patient has not engaged in heavy exercise, smoked, or had caffeinated drinks in the prior 30 minutes. The patient's upper arm is measured, with patients whose arms are <22 cm or >42 cm excluded (the home BP monitor has not been validated for these arm sizes). Patients rest for at least 5 minutes before measurement, sit in a chair with back support, arm supported at heart level, with BP measured twice one minute apart using the validated Omron 907 automated BP monitor.¹⁹ Patients with systolic BP > 140 mmHg or diastolic BP > 90 mmHg on both BP measurements are eligible to participate (e.g., if the first BP is 155/85 and the second BP is 138/85 the patient is not eligible). Patients whose average BP is systolic > 180 or diastolic > 110 mmHg BPs on two measurements are excluded and instructed to make an appointment with their primary care physician. All participants (ineligible, eligible, and those who decline

participation) receive \$20 at the end of screening visit (visit 1). Participants eligible to participate are asked to sign informed consent, complete the first survey on a tablet computer (with the same method used for collecting patient self-reported data at subsequent visits), and then are randomized to one of the 3 diagnostic BP measurement methods. They are given training and information specific to each method and receive an additional \$20 at the completion of visit 1.

Randomization

A computer-based randomized sequence generator is used to 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 ≤150 or >150 mmHg), using block sizes of 3 or 6 within each stratum (to assure that randomization is concealed). The randomization sequence is built into the database and does not run until BP data (which meets eligibility criteria) is entered and the baseline survey is completed. The computerized randomization schema and process are concealed to study staff.

Interventions

Consented participants are randomized to Clinic BP, Home BP, or Kiosk BP groups and asked to complete specific BP monitoring regimens based on usual care (Clinic BP arm), or existing evidence and national guidelines for diagnostic testing (Home BP and Kiosk BP arms, Appendix).

Clinic BP Arm—Clinic BP participants are asked to return to their regular clinic to have their BP checked as per usual clinical care, with the standard being that patients with high BP return for additional visits until BP is normal, regardless of whether or not hypertension has been diagnosed and treated. Patients receive verbal and written instructions customized to each clinic's usual procedure for follow-up BP checks. BP check visits at KPWA are generally done by medical assistants or nurses either using validated wall mounted aneroid BP monitors (Welch Allyn Tyco™) or validated automated BP monitors (GE Carescape 100™). KPWA does not charge co-pays for follow-up medical assistant or nurse BP visits. Clinic providers enter BP measurements into the EHR. If the BP is measured more than once, the standard is to enter each BP measurement. KPWA provides BP measurement training guidelines and signage for properly measuring BP but use of these procedures and materials is left to the clinics. KPWA engineers inspect automated BP monitors annually. The clinics are responsible for maintenance of the aneroid BP monitors.

Home BP Arm—Home BP participants receive a validated, automated Omron N786 BP monitor with an upper-arm cuff appropriate for their arm size.^{20, 21} They are instructed to avoid caffeinated beverages and heavy exertion prior to measuring their BP; to rest for 5 minutes; sit with their arms, back, and legs supported; and apply the cuff correctly to their bare arm (left arm, unless there is a reason for using the alternate arm) with their arm at the level of the heart. Participants are then asked to demonstrate the process to study staff while taking their own BP to demonstrate comprehension.

Home BP participants receive additional verbal and written instructions about their home monitoring schedule. Home BP participants are asked to obtain 20 BP measurements, with 2 measurements in the morning and 2 measurements in the evening for 5 days. The preferred routine is for the patient to measure their BP upon arising in the morning and before they go to bed (to capture the diurnal pattern of BPs). Participants are able to see their BP readings on the monitor's screen and as well as prior BP measurements including the date and the time it was recorded, with all BPs measurements stored in the monitor's memory function (BPs cannot be deleted). They are instructed not to share their monitor with others and asked to bring the BP monitor to the second research visit, at which time the BP measurements are uploaded to a secure website. Omron sends the study staff reports of participant BP data with no identifiers other than participants' study ID, BP, pulse, time, and date.

Kiosk BP Arm—Kiosk BP participants are asked to take their BP on the validated PharmaSmart BP kiosk at their clinic or any of 60 pharmacies in the same region as the participating clinics (at a local pharmacy chain that uses PharmaSmart BP kiosks).^{22, 23} They are given a PharmaSmart smart card and asked to use it each time they take a kiosk BP which allows linkage of the BPs to the respective participant. Each participant randomized to the Kiosk BP arm receives step-by-step instruction on measuring their BP using the BP kiosk with their smart card and are asked to demonstrate to study staff 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 arm 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 are asked to return to a kiosk and measure there BP 3 additional times at each visit on 3 separate days, for a total of 9 BP measurements (not including the training measurements). PharmaSmart sends the study staff reports of participant BP data with no participant identifiers other than the smart card ID, BP, pulse, time, and date stamp. PharmaSmart has no access to other participant data.

Research Visit 2—All participants are asked to return in approximately 3 weeks for a second research appointment. All participants receive a reminder call the week prior to the visit, to remind them of the appointment and to complete their assigned diagnostic protocol if they have not already done so.

At visit 2, participants take survey #2 and then begin the ABPM test using the validated Welch Allyn 7100 ABPM, which is programmed to measure BP every 30 minutes during the day and every 60 minutes during the night.²⁴ Participants are instructed to rest and refrain from talking while their BP is being measured and receive written instructions about ABPM testing (e.g., not to bathe with it on, avoid heavy exercise, and turn off the monitor after 24 hours of testing). Participants receive \$20 at the end of visit 2.

Research Visit 3—Participants return the next day, and the ABPM device data is uploaded. Participants are given preliminary results (Figure 3) with their average daytime BP written on an information sheet and are informed if their daytime mean ABPM is 135 mmHg systolic or 85 mmHg diastolic. The patient is then asked to take survey #3. Participants receive \$30 upon completing visit 3.

After the visit, the study physician reviews and interprets the ABPM test results, enters the result in an EHR encounter note, and routes this note to the patient's primary care provider (Figure 3) with the full ABPM report scanned into the EHR. The study physician tracks whether the ABPM report has been reviewed by the participant's physician and sends reminders to the provider until review of the report is acknowledged. Patients are mailed a copy of the report and receive a recommendation to make an appointment with their provider if the BP is elevated (daytime ABPM mean BP $\geq$ 135 mmHg systolic or $\geq$ 85 mmHg diastolic).

Research Visit 4—All participants return for a 4th final visit approximately 6 months after randomization. At this visit, the participant's weight and BP are measured (twice, using the same procedures as visit 1) and participants complete a 4th questionnaire. Participants receive \$30 at the end of the visit. Participants who were not assigned to receive the home BP monitor arm initially receive a validated Omron home BP monitor at the 6-month visit to thank them for their participation and provide equal incentives across the 3 diagnostic arms.

Outcomes (Tables 1 and 2)

Aim 1: To assess the comparability and accuracy of clinic, home, and kiosk BP to daytime ABPM (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 kiosks BPs transmitted via the Smart Card and obtained between visit 1 and 2, except for the 3 training BPs that occur at visit 1.

ABPM blood pressure 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 ABPM testing and provides additional data, but this and other data captured (e.g., nocturnal dipping, morning surge) are not used for the primary or secondary outcome assessments.

Aim 2: To compare the acceptability of clinic, home, kiosk, and ABPM 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 is measured as the percent of participants who complete their assigned BP testing protocol from the time of randomization to visit 2. Adherence is 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 ABPM is

defined as at least 14 daytime ABPM measurements.^{25, 26} BP measurements done as part of the research visits or patient training are not included in diagnostic accuracy and adherence assessments.

Patient-reported measures of acceptability of the BP diagnostic tests are 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 ABPM; and at 6 months (Table 2). Acceptability of diagnostic tests includes the 13-items questionnaire used by Little et al.,²⁷ 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 is 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 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;²⁸ health related quality of life using the Patient Reported Outcomes Measurement Information System (PROMIS) measure of general physical and mental health (Global Health [GH10])²⁹; and change in lifestyle behaviors, including questions on fruit and vegetable intake³⁰ physical activity³¹ and salt intake²⁹ (Table 2). Satisfaction with BP care is assessed using a single question from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey ("Using any number from 0–10, where 0 is the worst health care possible and 10 is the best health care possible, what number would you use to rate your blood pressure healthcare in the last 6 months?").^{32, 33}

BP outcomes at 6-months including receipt of a new hypertension diagnosis (based on a new ICD 10 diagnosis in the EHR; I-11, I-12, or I-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 2 and 3 Qualitative Assessments: To provide rich descriptive data on patient experiences with the different diagnostic testing methods, qualitative data are collected through patient interviews at three study clinics with approximately 12 patients from each arm (36 interviews in total). The final sample will include a balance of patients with high and average/low blood pressure. We will interview the same individuals at two time-points, once after receiving their ABPM report and a follow-up interview with the same patients approximately 6 months later. If interview participants are lost to follow up, we will replace them with individuals who meet the same sampling criteria (e.g. arm of study and BP). The goal 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, impact on stress, anxiety and concern about health, and interactions with healthcare teams.

We also will explore participant understanding of results they were given and their meaning, what they needed to do next, and what, if any, shared decision making occurred.

Aim 4: To examine provider knowledge, preferences, and beliefs about BP diagnostic tests pre- and post-study; to identify implementation barriers and facilitators for clinic, home, kiosk, and ABPM BP monitoring. To assess provider (physicians, nurses, medical assistants) knowledge, attitudes and beliefs, we are collecting surveys at the start of clinic participation in the study. Questions include knowledge, use, and beliefs about clinic, home, kiosk, and ABPM 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 ABPM report, to learn more about their experience of receiving hypertension diagnostic results.

Analytic Plan

Aim 1: To assess the comparability of clinic, home, and kiosk systolic blood pressure relative to ABPM, we will use linear regression models to estimate the mean difference in systolic BP (mmHg) between the diagnostic and the ABPM reference standard tests (primary outcome) for each randomization group. The dependent variable is the difference in systolic BP between the diagnostic and ABPM measures, and the independent variables of interest are indicators for randomization group. Regression models will 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.³⁴ To protect against multiple comparisons, we will use the Fisher protected least-significant difference approach,³⁵ which requires that pairwise group comparisons are made only if the overall omnibus test of any differences between groups is statistically significant. In addition to the regression model, we will use a Bland-Altman approach to assess the diagnostic accuracy of clinic, home, and kiosk BP relative to ABPM, by estimating the bias and 95% limits of agreement for each diagnostic test. We will use Bland-Altman plots to show the degree to which the two measures of BP (diagnostic measure vs. ABPM) differ and how this difference is related to the underlying BP measure.^{36, 37} Analysis of the difference in diastolic BP between diagnostic measures and ABPM will use the same methods described for systolic BP.

Secondary analyses will assess diagnostic accuracy of clinic, home, and kiosk BP measures, including estimation of sensitivity and specificity of each diagnostic test compared to the reference standard ABPM. To estimate sensitivity, we will fit a logistic regression model. The outcome variable is binary, indicating whether clinic, home, or kiosk BP was above the threshold for hypertension (positive test), and the model is fit using the subgroup with hypertension according to ABPM. To estimate specificity, the outcome variable indicates if the diagnostic BP was below the threshold for hypertension (negative test), and the model is

fit using the subgroup without hypertension according to ABPM. For the analysis of diagnostic accuracy, the thresholds for hypertension (yes/no) will be based on guideline established standards, with clinic as systolic BP ≥ 140 mm Hg and/or diastolic BP ≥ 90 mm Hg, and home, kiosk, and ABPM BP as systolic BP ≥ 135 mm Hg and/or diastolic BP ≥ 85 mm Hg. We will also perform exploratory analyses to assess sensitivity and specificity using other diagnostic thresholds, including those corresponding to the revised ACC/AHA guidelines. We will perform receiver operating characteristic curve analyses to determine how the test performance changes when we vary the threshold for hypertension for each diagnostic protocol. We will also estimate positive and negative predictive values (PPV and NPV) of clinic, home, and kiosk BP relative to the ABPM reference standard for a range of diagnostic thresholds.

Aim 2: The primary outcome for the assessment of acceptability of the diagnostic measurement methods is adherence to the diagnostic protocol (Table 2). To compare the proportion completing each diagnostic test to the proportion completing ABPM, we will fit a GEE model with identity link function and binomial error distribution to directly estimate the difference 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, kiosk, or ABPM). Each participant will contribute two observations to this analysis, one for adherence to ABPM, and one for adherence to their randomization diagnostic protocol. We will use a sandwich variance estimate to account for this participant-level correlation.³⁴ Model results will be reported as the difference in proportion completing testing protocol for home, kiosk, and ABPM, compared to clinic. We will use clinic as the reference group because this is the diagnostic method used most in clinical practice. 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 BP measurement method (home, clinic, kiosk, and ABPM). 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).

Aim 3 Analysis: To estimate changes over time in BP and patient-reported outcomes (e.g., anxiety, health related quality of life, and behavior change): we will construct linear regression models with change from baseline as the dependent variable. Models will include two records for each participant, one for the 1-month and another for the 6-month outcomes and will be fit using GEE to account for this correlation. To allow the intervention effect to change over time, the model will include both main effects for each group (Clinic, Home, or Kiosk) and time point (1-month or 6-month), and interaction between these variables. A separate model will be estimated for each patient outcome and will adjust for the baseline measure of the outcome and for baseline characteristics that are related at the α level of .10 to either the outcome or intervention groups.

In exploratory analyses, we will also use similar analytic methods to assess whether BP outcomes at 6-months, including receipt of a new hypertension diagnosis, systolic BP, diastolic BP, and BP control (average of two research BP taken at visit 4 $<140/90$ mm Hg),

and 6-month patient reported outcomes, vary by average daytime ABPM results (BP normal, borderline high, or 5 mmHg or more above the diagnostic threshold based on ABPM daytime average).

To handle missing outcome data for Aims 1–3, we plan to do a complete case analysis with adjustment for baseline covariate that are imbalanced by randomization group. However, if the follow-up rate is low (<85%) or there is differential attrition by randomization group or patient characteristics, we will consider missing data statistical methods such as inverse probability weighting or imputation³⁸ to account for potential bias caused by differential attrition. We will test for heterogeneity of effects by baseline BP and participant characteristics in subgroup analyses (e.g., sex, age group <50, 50–64, 65+, race/ethnicity, arm size, BMI, tobacco use). All analyses will use an intent-to-treat approach, with participants analyzed based on their randomization group, regardless of their study participation.

Aim 4: Analyses of responses to the baseline provider survey will be primarily descriptive, with summary statistics describing provider knowledge, preferences and beliefs about BP diagnostic tests before the study, including their knowledge of the USPSTF hypertension guidelines for diagnosing hypertension, and, if they are aware of the guidelines, to what degree they feel the guidelines are appropriate, acceptable, and feasible to implement.

Qualitative analyses (Patient and Provider interviews) will code interview transcripts using both a priori and emergent concepts.³⁹ Coding will be informed by a phenomenological approach to explore the experiential aspects of BP testing for both patients and providers. This approach focuses on understanding the essence or experience of a given phenomenon, from the perspective of the participants.^{40–42} Phenomenology is a helpful framework for analyzing the nuances of how patients and providers understand and react to their experiences and the decisions they make based on testing results. This approach will also help us examine how the study affected interactions among patients and providers using the domains of the Social Ecological model. The code list and codebook will be developed iteratively by conducting successive rounds of coding comparison between at least two coders to until a shared understanding of how to apply the codes and their definition is achieved (as evidenced by a high level of agreement between coders when coding independently and then comparing codes).

Statistical Power—With a sample size of 510 (170 per group) and assuming a protocol completion rate of at least 80%, evaluation of comparability of BP measures and test accuracy will be based on a sample size of 136 for each group (Aim 1). With this sample size, we can detect a 4.1 mmHg difference in systolic and a 2.8 mmHg difference in diastolic BP between any two groups (assuming a standard deviation of 12.1 mmHg systolic and 8.3 mmHg diastolic)²³. Adherence to testing protocol (yes/no) will be defined for all 510 randomized participants. Assuming an 80% adherence rate in one group, the least detectable difference is 11% for pairwise group comparisons (Aim 2). Finally, 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.

Results

Recruitment and enrollment

Recruitment and enrollment is performed one clinic at a time on a rolling basis. To invite clinics to participate, we send the medical director and clinical operations manager at each clinic the PCORI approved public abstract that describes the study and a description of what will happen at the clinic, including the placement of the kiosk in the waiting room, and the impact of study participation. Most clinics have enthusiastically agreed to participate in the study. One clinic chose not to participate, citing lack of staffing for extra MA or nurse BP checks, despite our modest projection of 15–20 additional visits over 3 months (5–7 per month). We find that it takes several weeks to set up in each new clinic, and it can be challenging to manage the transition when screening and enrollment visits begin in one clinic while participants are still completing study procedures at the previous clinic.

Another challenge is that we are finding fewer people than expected who agree to come to a screening visit, either by actively refusing (e.g., not interested or being too busy), passively refusing (not answering their phone or returning messages), or who are unable to be reached (e.g., no or the correct phone could be identified). Of those willing to come in for a screening visit, over half have had BPs <140 mmHg systolic and <90 mmHg diastolic threshold on one or both BP measurements, possibly in part because we adhere to recommended standards for BP measurement, i.e., 5 minutes of rest, and measuring arms for proper cuff fit. By increasing study sample, research staff, and the number of study screening visits, we remain on track of our goal of enrolling 510 patients with elevated BPs and no prior diagnosis of hypertension.

The first patient was enrolled into the study on May 11, 2017. As of June 15, 2018, 323, 64% of the planned 510 participants have been eligible, enrolled in the study, and randomized into one of the three diagnostic groups (Clinic BP, Home BP, Kiosk BP). Of the 323 enrolled participants, 270 have completed their 3-week follow-up research visits (with all but a few successfully completing ABPM), and 150 have completed their final 6-month follow-up research visit. We expect to be done with enrollment by early 2019, with 6-month follow-up visits completed by mid-2019.

Changes to BP Thresholds for Diagnosing Hypertension

BP thresholds for diagnosing hypertension US guidelines changed during the study.¹¹ Previously the threshold for making a new diagnosis of hypertension was an average clinic BP 140 mmHg systolic or 90 mmHg diastolic (at 2 visits, with 2 or more BPs averaged)⁴³ or a daytime ABPM or home BP average of BP 135 mmHg systolic or 85 mmHg diastolic, thresholds that account for the differences between clinic and out of office readings (both systolic and diastolic BP readings are approximately 5 mmHg lower when

measured outside of a clinic setting). The new guidelines sponsored by the American College of Cardiology and the American Heart Association (ACC/AHA), which were released in November 2017 recommended that the BP threshold for diagnosing hypertension be lowered to 130 mmHg systolic or 80 mmHg diastolic for both in-clinic and out-of-office BP measures. BP-CHECK began recruitment, enrollment, and study procedures before these changes.

Our primary outcome is not dependent on a dichotomous threshold of 140/90 or 130/80. We measure BP differences between diagnostic methods as a continuous variable. Thus, our primary outcome will not be affected by the guideline changes. Our analytic plan will allow us to compare the accuracy of clinic, home, and kiosk BP compared to the reference standard ABPM at different diagnostic thresholds.

However, our 6-month outcomes, diagnosis, treatment, and BP control among participants with elevated BP on ABPM could be affected by the guideline changes. Our regional health care system (KPWA) has not yet recommended using out of office BPs for diagnosing hypertension. KPWA nephrologists oversee ABPM testing and continue to use average daytime BP of 135 mmHg systolic and 85 mmHg diastolic to make a new diagnosis of hypertension. Based on regional practices and the fact that as current our primary outcome will not be affected by guideline changes, we have made no changes to our protocol in response to the updated ACC/AHA Hypertension Guideline. Our Patient and Stakeholder Advisory Committee and DSMB endorsed this decision. Our mixed methods assessments will allow us to explore physician's knowledge about the USPTF and ACC/AHA guidelines for diagnosing hypertension and its impact on their attitudes and beliefs.

Discussion

BP measurement is the most common biometric measure assessed in clinic, but it is often performed incorrectly.⁴⁴ Even when performed properly, an individual's BP may vary according to the time of day and other factors (e.g. rest, anxiety) making it difficult to determine whether BP is normal or high. Recently the USPTF recommended out of office BP measurement, preferably ABPM, before a new diagnosis of hypertension is made. The new AHA/JACC hypertension guidelines likewise recommend use out-of-office BP measurement to inform diagnosis.¹¹ However, in the US, few primary care physicians use ABPM and most patients have not heard of it.

For each of our comparisons, we chose validated automated BP measurement devices that were most likely to be accurate based on our review of validation studies. However, automated BP monitors measure BP indirectly and BPs measured by one device might not be identical to those measured by an alternate automated device. Theoretically these differences should be small if validated BP monitors are used. As part of usual care, the study is not able to control BP measurement in clinic, but the organization purchases validated BP devices and has protocols for properly measuring BP.

We chose to compare clinic and HBPM to ABPM, with the hypothesis that HBPM will be superior to clinic-based methods for diagnosing hypertension. We elected to add kiosk BPs

as a comparator arm, as some patients might not be able to afford to purchase a monitor (although BP-CHECK participants receive home BP monitors initially in the Home BP arm and at the end of the study in the Clinic and Kiosk BP arms as an incentive for participating) or have the ability to follow the recommended protocols for obtaining multiple BPs at home, with disadvantaged populations being disproportionately affected.

Although our study has 4 aims, it is important to note that we have chosen only 2 outcomes, comparability of BP measures and acceptability of measurement protocols, as our primary outcomes (Aims 1 and 2). Aim 3, longer-term impact of diagnostic testing at 6 months, focuses on the downstream consequences of a hypertension diagnosis on patient-reported outcomes (distress, lifestyle change), and among those with hypertension diagnosed, whether BP is subsequently controlled, and the interaction between diagnostic arm and ABPM results on these outcomes. Aim 4 focuses on health care providers' knowledge, attitudes, and beliefs about BP measurement and diagnosing hypertension, and explores the feasibility of introducing and integrating new methods for diagnosing hypertension into primary care.

The recent change in BP thresholds for diagnosing hypertension in the U.S. poses challenges to our study. However, our primary outcome, comparative accuracy compares BP differences according to the diagnostic method as a continuous variable and will not be affected. We will assess the impact of different systolic and diastolic BP thresholds on hypertension diagnosis predictive values, and to define BP threshold for those whom ABPM might not provide any additive value. Our analytic plan thus will allow us to compare the accuracy of clinic, home, and kiosk BP at different diagnostic thresholds, including the new thresholds for stage 1 hypertension recommended by the ACC/AHA guidelines. Mixed methods assessments will allow us to explore physicians' knowledge, attitudes, and beliefs of the USPSTF and ACC/AHA guidelines.

Conclusion

Hypertension is the leading risk factor for cardiovascular disease, the most common cause of avoidable death and disability. Under-diagnosis of hypertension misses opportunities to help patients make choices and receive treatments that can potentially improve their health, wellbeing, and longevity. Over-diagnosis exposes people to the harms of unneeded medications and care. BP-CHECK will help minimize misdiagnosis. BP-CHECK will also address research gaps identified by the USPSTF, including the comparability, accuracy, and acceptability of different methods for diagnosing hypertension and the potential benefits and harms of making a new diagnosis of or ruling out hypertension.⁴⁵

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Appendix

Appendix Table:

Guidelines for Diagnosing Hypertension

Organization, Year	Diagnostic Protocol*	BP Threshold (mmHg)
Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults, 2017 (American College of Cardiologists, American Heart Association and other associations) ¹¹	Out of office BP measurements are recommended to confirm the diagnosis of hypertension Definitions of hypertension were changed: Stage 1 Hypertension Clinic BP = 130/80 Stage 2 Hypertension Clinic BP = 140/90	Stage 1 hypertension: HBPM and ABPM awake 130/80 = clinic 130/80 State 2 hypertension: HBPM and ABPM awake 135/85 = clinic 140/90
United States Preventive Services Task Force (USPSTF), 2015 ⁸	Before confirming a diagnosis of HTN, obtain out-of-office BP, preferably ABPM, with HBPM as an option. Protocol not stated.	Thresholds not stated
Canadian Hypertension Education Program (CHEP), 2017 ⁴⁶	New diagnosis of hypertension confirmed based on average BP <ul style="list-style-type: none"> • OBPM: 5 clinic visits for stage 1 HTN • OBPM: 3 clinic visits for stage 2 HTN • ABPM: 24-hour • HBPM: duplicate measures twice a day for 7 days, drop day 1, average of 6 days BP 	OBPM 140/90 ABPM awake 135/85, 24-hr 130/80 HBPM 135/85
National Institute for Health and Care Excellence (NICE), 2016 ⁴⁷	A diagnosis of HTN should be confirmed by out-of-office BP: daytime ABPM, HBPM at least 4 days (twice in the morning, twice in the evening), use average BP	ABPM awake 135/85 HBPM 135/85
Japanese Society of Hypertension, 2014 ⁴⁸	Home and ABPM measurements useful for diagnosing essential, white-coat, and masked hypertension. Home BP mean of 5–7 days of measurements	OBPM 140/90 ABPM awake 135/85, 24-hr 130/80, night 120/70 HBPM 135/85
World Hypertension League, 2014 ⁴⁹	Supports use of automated BP monitors, discourages manual BP monitors for diagnosis and care of high BP. Endorses ABPM, but ABPM is not globally available. Endorses community BP kiosk use. Protocol not stated.	Thresholds dependent on 10-year risk for CVD
American Society of Hypertension, 2014 ⁵⁰	Diagnosis of HTN should be confirmed at an additional clinic visit, 1–4 weeks after first measurement	OBPM 140/90 HBPM 135/85
European Society of Hypertension, 2013 ⁵¹	ABPM or HBPM is recommended for borderline or variable office BPs. HBPM 3–4 days, preferably 7 days, (twice in the morning, twice in the evening), use average BP	ABPM awake 135/85, 24-hr 130/80, night 120/70 HBPM 135/85
Joint Statement of the American Hypertension Society, American Heart Association, and Preventive Cardiovascular Nurse Association, 2008 ⁵²	Assessment of white-coat HTN: HBPM for 7 days, 2 measurements twice a day, drop day 1, average of 24 measurements	HBPM 135/85
Joint National Committee on Prevention, Detection, Evaluation, and Treatment of Blood Pressure (JNC 7), 2003 ^{7,43}	Stage 1 HTN should be confirmed within 2 months of the initial elevated clinic BP; Stage 2 within 1 month.	OBPM 140/90 ABPM awake 135/85

* All guidelines recommend using upper arm BP monitors

+ JNC 8 did not address diagnosis of HTN

White coat HTN: high in clinic, low out of clinic; masked HTN: low in clinic, high out of clinic

Abbreviations: HTN = hypertension, BP = blood pressure, OBPM = office (clinic) BP measurement, ABPM = 24-hour ambulatory BP measurement, CVD = cardiovascular disease, HBPM = home BP measurement

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Figure 1:
BP-CHECK Consort Flow Diagram

Figure 2:
Conceptual Model of Factors that Impact Different Methods for Making a New Diagnosis of Hypertension

Welch Allyn CardioPerfect Workstation – BP Check Research Study 24 Hour Ambulatory Test Report

Name: Recorded: 10/12/2017 8:34:18 AM
 Number: Read back: 10/13/2017 8:30:00 AM
 Gender: Female Reviewed by: Dr. XX
 Birthdate: 4/6/1959 58 years
 Comment:

IMPRESSION:

The patient's average daytime BP is **elevated**** (consistent with a new diagnosis of hypertension or hypertension with uncontrolled BP).

Threshold for elevated blood pressures using 24 hour ambulatory BP monitoring:

- $\geq 130/80$ for 24 HOUR
- $\geq 135/85$ for DAY
- $\geq 120/70$ for NIGHT

The threshold for elevated BP in clinic is $\geq 140/90$

Note in some populations target blood pressures may be lower (e.g. patients with reduced kidney function [eGFR 20-59 mL/min/1.73 m²] - or patients with an aneurysm) or higher (e.g. age 60 or over and no cardiovascular disease risk factors) than the cutoffs used for this interpretation

General:	Overall:	Awake:	Asleep:
Nr. measurements	41	31	10
% Succeeded	95%	94%	100%
Total time	23:49:00	14:49:00	09:00:00
Average	160 / 84 mmHg	163 / 84 mmHg	152 / 82 mmHg
SD	18.5 / 10.5 mmHg	19.0 / 11.3 mmHg	14.4 / 7.7 mmHg
Pulse Pressure	76.6 mmHg	78.9 mmHg	69.6 mmHg
Systolic:			
Nr. measurements	40 (98%) ≥ 130	29 (94%) ≥ 135	10 (100%) ≥ 120
Maximum	210 mmHg at 20:30	210 mmHg at 20:30	187 mmHg at 7:30
Minimum	122 mmHg at 15:30	122 mmHg at 15:30	132 mmHg at 2:00
Diastolic:			
Nr. measurements	29 (71%) ≥ 80	14 (45%) ≥ 85	9 (90%) ≥ 75
Maximum	104 mmHg at 14:30	104 mmHg at 14:30	94 mmHg at 6:00
Minimum	61 mmHg at 9:03	61 mmHg at 9:03	66 mmHg at 2:00
Heart rate:			
Average	74 bpm	74 bpm	76 bpm
SD	5.6 bpm	5.3 bpm	6.3 bpm
Maximum	87 bpm at 7:00	84 bpm at 9:03	87 bpm at 7:00
Minimum	66 bpm at 9:30	66 bpm at 9:30	68 bpm at 1:00
Awake/asleep decrease, early morning:			
Decrease:	7.1% / 2.8% (Not a dipper)		
Morning average:	184.0 / 73.5 mmHg		

Figure 3:
 Example of the 24-Hour Report Sent to Patient Participant's Physician

Table 1:**BP-Check Aims and Outcomes**

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

BP = blood pressure; SBP = systolic BP; DBP = diastolic BP; ABPM = 24-hour ambulatory BP; EHR = electronic health record

Table 2
BP-CHECK Patient Questionnaires (Patient-reported Measurements)

Questionnaires are administered to participants at visit 1 (baseline), visit 2 (Pre-24hr BP), visit 3 (Post-24hr BP), and visit 4 (6-month follow-up).

Measure	Items	Visit	Source
BP diagnostic testing regimen acceptability	7	1, 2, 3	7-Items developed for the study
BP diagnostic testing regimen acceptability	13	1, 2, 3	Little P, Barnett J, Barnsley L, et al. Comparison of acceptability of and preferences for different methods of measuring blood pressure in primary care. <i>BMJ</i> . 2002 Aug 3; 325(7358):258–9. PMID: PMC117641.
Confidence in BP measurements	4	2, 3	Viera AJ, Tuttle LA, et al. Comparison of patients' confidence in office, ambulatory, and home blood pressure measurements as methods of assessing for hypertension. <i>Blood Press Monit</i> . 2015 Dec;20(6):335–40. PMID: PMC4631691.
Perception of comparative accuracy	5	1, 2, 3, 4	Little P, Barnett J, Barnsley L, et al. Comparison of acceptability of and preferences for different methods of measuring blood pressure in primary care. <i>BMJ</i> . 2002 Aug 3; 325(7358):258–9. PMID: PMC117641.
Preference for BP testing regimen	1	1, 2, 3, 4	Little P, Barnett J, Barnsley L, et al. Comparison of acceptability of and preferences for different methods of measuring blood pressure in primary care. <i>BMJ</i> . 2002 Aug 3; 325(7358):258–9. PMID: PMC117641.
BP monitoring or measurement outside of clinic visits	5	1, 4	Adapted from Electronic Communication and Home Blood Pressure Monitoring Trial (eBP) Green BB, Cook AJ, et al. Effectiveness of home blood pressure monitoring, Web communication, and pharmacist care on hypertension control: The e-BP randomized controlled trial. <i>JAMA</i> . 2008 Jun 25;299(24):2857–67. PMID: 2715866
Fruit and vegetable intake	1	1, 2, 4	Beresford's single item fruit and vegetable pictographic tool. Beresford SA, Thompson B, Feng Z, Christianson A, McLerran D, Patrick DL. <i>Seattle 5 a Day Prev Med</i> . 2001 Mar;32(3):230–8. PubMed PMID: 11277680.
Physical activity	1	1, 4	Marcus BH, Selby VC, Niaura RS, Rossi JS. Self-efficacy and the stages of exercise behavior change. <i>Res Q Exerc Sport</i> 1992; 63(1):60–6
Salt intake	3	1, 2, 4	Margolis KL, Asche SE, et al. A Successful Multifaceted Trial to Improve Hypertension Control in Primary Care: Why Did It Work? <i>J Gen Intern Med</i> . 2015 Nov;30(11):1665–72. PMID: PMC4617923.
Tobacco use	5	1, 4	Fiore MC, Jaén CR, Baker TB, et al. <i>Treating tobacco use and dependence: 2008 update. Clinical practice guideline</i> . Rockville, MD: U.S. Department of Health and Human Services. Public Health Service; 2008.
Alcohol use	3	1, 4	Bischof G, Grothues J, et al. screening in general practices using the AUDIT: how many response categories are necessary? <i>Eur Addict Res</i> . 2007;13(1):25–30. PubMed PMID
PROMIS Global Health	10	1,2,4	Hays, R. D., Bjorner, J., Revicki, R. A., Spritzer, K. L., & Cella, D. (2009). Development of physical and mental health summary scores from the Patient Reported Outcomes Measurement Information System (PROMIS) global items. <i>Quality of Life Research</i> , 18(7), 873–80.
Perceived risk and impact of stroke/heart attack	6	1,2,4	McClure JB, Ludman E, Grothaus L, Pabiniak C, Richards J, Mohelnitzky A. Immediate and short-term impact of a brief motivational smoking intervention using a biomedical risk assessment: The Get PHIT trial. <i>Nicotine Tob Res</i> . 2009 Apr; 11(4):394–403. PMID: PMC2670368.
PROMIS Global Health	10	1,2,4	Hays, R. D., Bjorner, J., Revicki, R. A., Spritzer, K. L., & Cella, D. (2009). Development of physical and mental health summary scores from the Patient Reported Outcomes Measurement Information System (PROMIS) global items. <i>Quality of Life Research</i> , 18(7), 873–80.
Worry/impact and about high BP	2	1, 2, 4	Developed for study
State Anxiety 6 (STAI-6)	6	1, 2, 3, 4	Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI). <i>Br J Clin Psychol</i> . 1992 Sep;31 (Pt 3):301–6. PubMed PMID: 1393159.
Impact of Events Scale	4	1, 2, 3, 4	Horowitz M, Wilner N, Alvarez W. Impact of Event Scale: a measure of subjective stress. <i>Psychosom Med</i> . 1979 May;41(3):209–18. PubMed PMID: 472086.

Measure	Items	Visit	Source
			*NOTE: full Impact of Events Scale is 15 items. For this study we have selected a subset of the 4 most relevant questions.
Perceived risk and impact of stroke/heart attack	3	1, 4	McClure JB, Ludman E, Grothaus L, Pabiniak C, Richards J, Mohelnitzky A. Immediate and short-term impact of a brief motivational smoking intervention using a biomedical risk assessment: The Get PHIT trial. <i>Nicotine Tob Res.</i> 2009 Apr; 11(4):394–403. PMID: PMC2670368.
Satisfaction with BP care	1	1,2,4	Adapted from https://cahps.ahrq.gov/surveys-guidance/cg/visit/index.html