Pilot and Feasibility Studies

STUDY PROTOCOL

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Adapting self-measured blood pressure monitoring to reduce health disparities (ASPIRE): a pilot hybrid effectiveness-implementation study protocol

Rasha Khatib[1*], Nicole Glowacki[1], Iridian Guzman[1], Maureen Shields[1], Joseph Chase[1] and Melanie Gordon[2]

Abstract

Background Hypertension is the leading risk factor for cardiovascular disease (CVD). Despite advances in blood pressure management, significant racial and ethnic disparities persist, resulting in higher risks of stroke, heart disease, and mortality among non-White populations. Self-measured blood pressure (SMBP) monitoring, also known as home blood pressure monitoring, has shown promise in improving blood pressure control, especially when combined with feedback from healthcare providers. However, the adoption of SMBP remains low, particularly among racial and ethnic minorities, due to various patient, provider, and system-level barriers.

Objectives This study aims to evaluate the feasibility of study methods implementing the ASPIRE (adapting self-measured blood pressure to reduce health disparities) toolkit in a primary care setting. The toolkit is designed to address barriers to SMBP adoption and improve hypertension management among underserved populations to increase SMBP adoption.

Methods This pilot hybrid effectiveness-implementation randomized controlled trial (RCT) will be conducted at a primary care clinic in South Side Chicago, serving a diverse patient population. Eligible patients with uncontrolled hypertension will be randomized to either the intervention group, receiving the ASPIRE toolkit and support, or the control group, receiving usual care. The primary outcomes include feasibility measures including recruitment rates, attrition, and availability of data in the electronic health records.

Results The feasibility of the study methods will be analyzed to inform a larger multi-site RCT informed by progression criteria developed in this protocol. Qualitative interviews with patients and providers will explore the appropriateness and implementation success of the toolkit using the Consolidated Framework for Implementation Research (CFIR).

Conclusions This pilot RCT will provide critical insights into the feasibility of study methods to evaluate the implementation success of the ASPIRE toolkit in a real-world primary care setting. By addressing barriers to SMBP adoption, this intervention has the potential to improve hypertension management and reduce health disparities in underserved populations.

Trial registration NCT: NCT06175793. Registered 19 December 2023, https://clinicaltrials.gov/study/NCT06175793.

Keywords Primary care, Hypertension, Social determinants of health, Self-measured blood pressure monitoring

*Correspondence:
Rasha Khatib
rasha.alkhatib@aah.org
Full list of author information is available at the end of the article

Introduction

Hypertension is the most common risk factor for heart disease globally and in the United States (US). Despite overall improvements in blood pressure management in the US, racial/ethnic disparities persist resulting in a greater risk of stroke, heart disease, and mortality among patients who do not identify as non-Hispanic White [1–3]. One potential intervention to improve blood pressure control is the use of self-measured blood pressure (SMBP), also known as home blood pressure monitoring. SMBP coupled with feedback from the care team to start or intensify medications leads to improved blood pressure control [4–6]. This is because patients are more engaged in their health management [4]. Taking multiple readings also increases the team's confidence in the measurements and allows for more opportunities to modify medications and provide counseling on adhering to a healthier lifestyle [7].

SMBP has been recommended in clinical practice guidelines as a strategy to increase blood pressure control [5]. However, implementing it in the real world, outside of small research studies with controlled environments has been difficult. Less than 50% of patients with hypertension in the US said they have taken their blood pressure measurements at home [8, 9]. Adoption among racial and ethnic minorities who suffer the greatest burden of hypertension is minimal. SMBP adoption is complex, and barriers are multifaceted at the patient, provider, and health system levels. Lack of availability or affordability of an appropriate device and lack of knowledge or skills to use the device have been reported by patients as major barriers. At the provider level, the lack of an efficient workflow to receive the readings from the patient to incorporate them into hypertension management has been reported. At the health system level, barriers reported relate to difficulties in documenting readings and a lack of technology resources to integrate SMBP devices that are connected to smartphone applications or that automatically transmit readings to the medical charts. These barriers are especially common in primary care settings serving underserved patient populations where resources are already limited and where patients report multiple social needs related to transportation, housing, and financial insecurity.

There is a need for an implementation toolkit that can be coupled with standard blood pressure devices, which many healthcare systems offer to their patients for free as a strategy to improve SMBP monitoring. We developed the ASPIRE (adapting self-measured blood pressure to reduce health disparities) implementation toolkit in response to this gap using customer discovery and value proposition methods. These methods build on marketing and LeanStartup business methods [10] for stakeholder engagement and are used to understand the clinical problem and articulate the product's hypothesized unique value proposition relative to alternative options available to the end user [11, 12]. Customer discovery aims to determine if there are actual customers for the health intervention in question, and value proposition design aims to ensure "problem–solution fit" in the development phase to derive value for the user [11].

Given the limited adoption of SMBP monitoring strategies, this study's main objective is to evaluate the feasibility of study methods of testing the ASPIRE implementation toolkit in a primary care setting compared to usual care. Results will inform a large multi-site hybrid effectiveness-implementation RCT to evaluate the implementation success of the ASPIRE toolkit in primary care settings.

Methods

Study design

This is a protocol for a pilot hybrid effectiveness-implementation randomized controlled trial (RCT). The protocol is reported following extension guidelines to the Consolidated Standards for Reporting and Writing a pilot or feasibility trial and the standards for reporting implementation studies statement [13, 14]. See Supplement 1 for the SPIRIT checklist, *ClinicalTrials.gov identifier NCT06175793.*

Study setting

This pilot RCT will take place at Advocate Health Care, a large integrated not-for-profit healthcare system in Illinois. The study team is collaborating with Advocate's Population Health Department to conduct this pilot as part of a program to distribute free blood pressure kits (cuff and machine) in primary care sites. For feasibility purposes, the study team identified one of the sites (purposive sampling) to conduct the pilot. The selected site is on the South Side of Chicago and serves a racially and ethnically diverse patient population.

In collaboration with the clinical team at the ASPIRE site, the study team will identify an exam room to be dedicated to the study. The study will recruit and randomize patients 3 days a week from patients of five internal medicine physicians and their residents in their 1st–4th year of training. Given the pragmatic nature of the trial, the study team and the clinical team will meet regularly to prepare for the study and to ensure that the study workflow fits within the clinic's workflow. These meetings will continue throughout the study.

Study participants

Given the pragmatic nature of this pilot and to ensure the generalizability of the intervention, all patients who are potential candidates to receive SMBP monitoring will be considered eligible [15]. This includes patients who attend the clinic on one of the three assigned days if they are (1) 18 years or older at the time of the visit, (2) have a hypertension diagnosis documented in the chart before this visit, (3) present with uncontrolled blood pressure defined as systolic blood pressure (SBP) of 140 mmHg or greater or diastolic blood pressure (DBP) of 90 mmHg or greater, and (4) and are prescribed one or more blood pressure-lowering medication. Patients will be excluded if they (1) were scheduled to attend but were a no-show, and (2) patients residing in a nursing home or receiving home health care will be excluded.

Recruitment and randomization

Physicians will be provided with a short script to introduce the study to potentially eligible patients. Interested patients will be escorted to a study-designated room where a trained research assistant will be available to confirm eligibility, recruit, consent, and randomize the patient on the same day. Written informed consent will be obtained from the patients by the research assistant. After consenting, patients will be randomly assigned in a 1:1 ratio to the intervention group or control group. Random group assignments will be generated by the study epidemiologist using SAS (PROC PLAN for assignment of two treatments). These group assignments will then be sealed in opaque envelopes and opened sequentially by the research assistant to ensure allocation concealment.

Sample size

This pilot trial evaluates the feasibility and acceptability of the ASPIRE implementation toolkit and trial methods among patients and providers in primary care settings. We also want to gain initial estimates on the adoption of SMBP monitoring. We will aim to recruit 50 patients for this trial to be randomized to the intervention (25 patients) or control (25 patients) arm. Previously established guidelines report that a minimum of 20 participants should be included in a pilot study but recommend at least 50 participants [16].

Ethical considerations

The study was approved by Advocate Aurora Health Institutional Review Board (IRB protocol no. 00104818) on 11/2/2023. Written, informed consent will be obtained from all participants as described in this protocol. Information about the study's significance, purpose, procedures, risks, and benefits will be provided to all eligible patients during the consent process.

Intervention arm

Patients randomized to the intervention arm will receive the ASPIRE implementation toolkit (Fig. 1). The toolkit components will be delivered to the patient at baseline, which is in-person after they see their primary care provider, over the phone, at 7 days, and, if needed, 14 days after baseline (Fig. 2). At baseline, the patient will receive the free blood pressure device (upper arm blood pressure monitor HEM-91210 T) [17] with the appropriately sized cuff and an SMBP monitoring log. This is a valid device that produces accurate readings per the American Medical Association guidance [18]. The patient will also be trained to use the device and how and when to document readings in the log. The patient will also be asked about

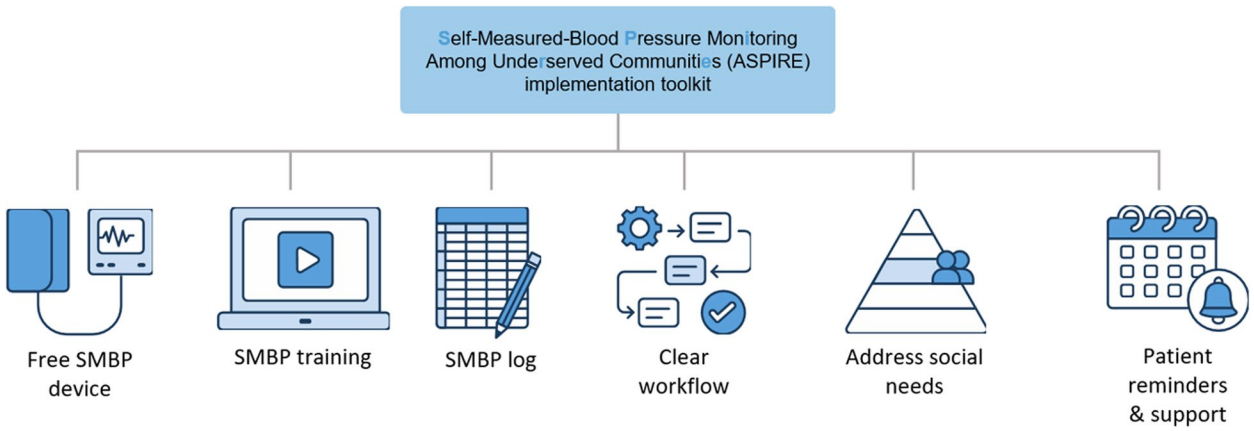

Fig. 1 ASPIRE implementation toolkit: *A*dopting *S*elf-Measured-Blood *P*ressure Mon*i*toring Among Under*s*erved Communities. *SMBP* self-measured blood pressure

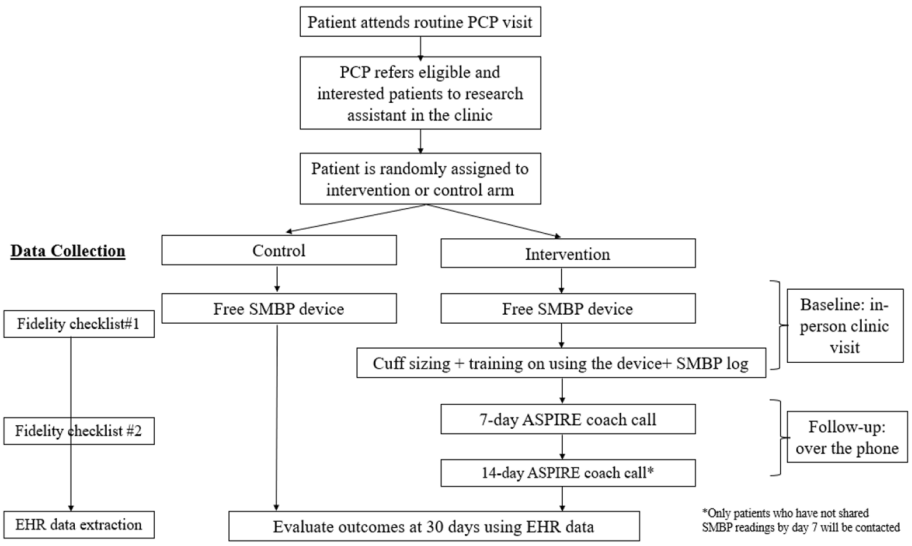

Fig. 2 Study flow. PCP, primary care provider

their preference on how to return the readings to the care team (i.e., over the phone, a picture of the log to share via a patient portal message, bring the completed log to the next visit). The patient will also complete a short social needs screening form to identify if the patient has any social needs related to housing, transportation, food and nutrition, or paying utility bills. At 7 days, the ASPIRE coach, a designated clinic staff member who will receive training on ASPIRE, will reach out to the patient over the phone. The ASPIRE coach will follow up on any questions the patient may have related to SMBP monitoring and will ensure the patient has identified a method to share the readings back with the clinic once the log is complete. If the patient has any social needs identified, the ASPIRE coach will address these needs by providing links to community-based organizations that match the patient's needs and are in the patient's same area of residence. If on day 14 the patient has not yet returned their readings, the research assistant will make a phone call to follow up with the patient on any challenges they may have encountered and encourage them to take and share SMBP readings with their care team.

Control arm

Patients randomized to the control arm will receive a free blood pressure device and will receive care as usual. This typically does not include BP cuff sizing or device training. The patient may receive a log from their provider to document readings at home, but no clear instructions are available in the log on how many readings to provide or how/when to share the readings back with the care team.

Outcome measures and analysis

The feasibility of the study methods, defined as the extent to which the research can be effectively carried out in a primary care setting serving underserved patient populations, will be assessed by patient recruitment rates and retention in the study. Reasons for declining to participate will be documented to inform the larger trial. Eligibility will be determined using electronic health records. Retention rates will be defined as the proportion of patients who had a follow-up visit to the clinic with at least one documented ambulatory blood pressure reading in the electronic health record within 3–6 months after consent. This outcome will inform the feasibility of collecting data for the larger trial on the change in blood pressure using electronic health record data.

*The appropriateness of implementation strategies*will be evaluated using qualitative interviews guided by the Consolidation Framework for Implementation Research (CFIR) [19]. Relevant constructs within each of the five domains of CFIR will be used to identify factors associated with implementation during semi-structured interviews conducted with patients randomized to the intervention arm and with care team members including primary care providers and clinic staff.

*Change in systolic blood pressure*will be explored to inform the sample size calculation of a larger trial and will be calculated by subtracting the baseline ambulatory

Table 1 Progression criteria to determine a larger trial

	Proceed with a larger trial	Amend — proceed with a larger trial	Stop — do not proceed unless changes are possible
Patient recruitment Can 50 patients be recruited from the pilot site?	If 50 patients are recruited during a 5-month recruitment period	If 25 patients are recruited during a 5-month recruitment period	If less than 10 patients are recruited during the 5-month recruitment period
Patient retention Do at least 80% of recruited patients return to the site within 3–6 months with at least one blood pressure reading recorded in the EHR?	If at least 40 (80%) of recruited patients return within 3–6 months and have a recorded blood pressure reading in the EHR	If at least 35 (70%) of recruited patients return within 3–6 months and have a recorded blood pressure reading in the EHR	If less than 35 (< 70%) of recruited patients return within 3–6 months and have a recorded blood pressure reading in the EHR
Appropriateness of implementation strategies	Strong interest in using the ASPIRE toolkit by patients and providers based on qualitative interviews	Strong interest in using the ASPIRE toolkit by patients and providers based on qualitative interviews	Limited or no interest in using the ASPIRE toolkit by patients and providers based on qualitative interviews

ASPIRE, *A*dopting *S*elf-Measured-Blood *P*ressure Mon*i*toring Among Under*s*erved Communities; *EHR*, electronic health record

blood pressure reading from the 30-day or most recent ambulatory reading (both extracted from electronic health records). If a reading at 30 days is not available, the closest available reading will be used. Medication intensification between baseline and 30 days will also be explored and calculated using the standard-based method, scored on a scale from − 1.0 to 1.0, with − 1.0 being the least amount of intensification and 1.0 being the most [20].

Progression criteria

A set of criteria was developed to create the progression criteria to proceed from this pilot to a larger more definitive trial. Discussions were held within the study team and were guided by progression criteria guidance in the literature, study team expertise in leading trials in primary care, and prior qualitative studies conducted on barriers and facilitators to hypertension management in primary care [21–25]. Qualitative and quantitative data will be collected during this pilot to evaluate the progression criteria outlined in Table 1 which includes the feasibility of patient recruitment and patient retention and appropriateness of implementation strategies.

Data collection

Quantitative data will be collected from the EHR at the end of the study. Data collected will include baseline demographic and clinical characteristics and blood pressure medications, ambulatory, and self-reported blood pressure readings for 30 days (+/− 10 days) after consent. Two fidelity checklists will be completed for each patient, and the first checklist will be completed by the research assistant to consent the patients and deliver the first part of the intervention. The second checklist will be completed by the ASPIRE coach who will deliver the second part of the intervention. The fidelity checklists will be used to evaluate any potential for contamination between the intervention and control arms. Training and data monitoring will also be employed to avoid potential contamination. Qualitative data will be collected through semi-structured interviews at the end of the study among patients randomized to the intervention arm, PCPs, and clinic staff including the assigned ASPIRE coach. All data collected, including the analytic dataset, will be stored on locked computers and only accessed by study team members as designated on the delegation log.

Statistical methods

A mixed-methods study design will be used for data analysis. Quantitative data will be analyzed using intention-to-treat. Description of the patient population, feasibility of study methods, and implementation success will be evaluated using descriptive statistics. Categorical data will be presented as numbers, percentages, and confidence intervals. For continuous data, variables with parametric distribution will be presented as means with standard deviations (SD), and variables with non-parametric distribution will be presented as medians with interquartile ranges (IQR). Interim analysis is not planned and will not be conducted.

For qualitative data analysis, interviews will be analyzed by inductive coding (reading through raw textual data to develop concepts and themes through interpretations based on the data), content analysis (determining the presence of certain words, themes, and/ or concepts within the data), and thematic analysis (identifying common themes including topics, ideas, and patterns that come up repeatedly). Interview transcripts will be uploaded, and codes will be applied via Dedoose V. 9.0.17 (Sociocultural Research Consultants, LLC; Los Angeles, CA, USA, 2021), an application for managing, analyzing, and presenting qualitative and mixed-method research data. Response codes will be used to organize qualitative data and identify themes. Coding will be done independently by two members of the study team to ensure data credibility. Code application frequencies will be analyzed using the code application chart in Dedoose, a feature used to count the number of times each code is applied to an excerpt, which will help the study team identify patterns within the interview data.

Discussion

This paper describes a pilot study to test the feasibility of study methods to evaluate the implementation success of a toolkit to support SMBP monitoring in primary care settings. The effectiveness of SMBP monitoring has been established across multiple RCTs. To fully realize the public health benefits of SMBP monitoring, it is important to further advance its reach and adoption, especially among underserved patient populations where hypertension and its clinical consequences are high. The available studies that explored the implementation of SMBP monitoring have mostly relied on interventions that require substantial information technology investments from primary care clinics (e.g., enhanced SMBP monitoring devices connected to smartphone applications). Our proposed pilot study evaluates the feasibility of implementing the ASPIRE SMBP toolkit in primary care settings. The toolkit is adaptable to the primary care setting and is tailored to standard SMBP devices that are more affordable to patients. Results from this pilot will inform a larger multicentered trial to provide results that are more generalized to large healthcare systems on the implementation success of the ASPIRE implementation toolkit.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-024-01588-z.

Additional file 1. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents.

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Authors' contributions
RK conceived the study, led the protocol development, and summarized the study methods for this publication. NG, IG, and MG provided intellectual input to the study design, methods, and evaluation. All authors contributed to, reviewed, and approved the manuscript.

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Data availability
The protocol, consent material, and datasets used during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by Advocate Aurora Health Institutional Review Board. Every participant will actively agree to be part of the study, and informed consent will be obtained according to the Helsinki Declaration.

Consent for publication
All authors carefully read the manuscript and approved it for publication.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]Advocate Health, Advocate Aurora Research Institute, Milwaukee, WI 53233, USA. [2]Advocate Christ Medical Center, Advocate Health, Oak Lawn, IL, USA.

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