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Collaboration Oriented Approach to Controlling High blood pressure (COACH) in adults: A Randomized Controlled Trial

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Title: Collaboration Oriented Approach to Controlling High blood pressure (COACH) in adults: A Randomized Controlled Trial

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Abstract

Introduction Hypertension, the clinical condition of persistent high blood pressure (BP), is preventable yet remains a significant contributor to poor cardiovascular outcomes. Digital self-management support tools can increase patient self-care behaviors to improve BP. We created a patient- and provider-facing clinical decision support (CDS) application, called the Collaboration Oriented Approach to Controlling High BP (COACH), to integrate home BP data, guideline recommendations, and patient-centered goals with primary care workflows. We leverage Social Cognitive Theory principles to support enhanced engagement, shared decision-making, and self-management support. This study aims to measure the effectiveness of the COACH intervention and evaluate its adoption as part of BP management.

Methods and analysis. Study design is a **multi-site,** two-arm hybrid Type III implementation randomized controlled trial set within primary care practices across three health systems. Randomized participants are adults with high BP for whom home BP monitoring is indicated. The intervention arm will receive COACH, a digital intervention with enhanced **affectively enhanced** alerts and displays intended to drive engagement with BP lowering; the control arm will receive COACH without the alerts and a simple display. Outcome measures include BP lowering (primary) and self-efficacy (secondary). Implementation pre-planning and post-evaluation uses the Consolidated Framework for Implementation Research and RE-AIM metrics with iterative cycles for qualitative integration into the trial and its quantitative evaluation. Trial analysis includes logistic regression and constrained longitudinal data analysis.

Ethics and Dissemination. The trial is approved under a single IRB. Dissemination of the intervention specifications and results will be through open-source mechanisms.

Strengths and limitations of this study

Limitations

- The study's utilization of participants solely from three academic health centers in the United States might restrict the applicability of the results to wider demographics.
- The eligibility criteria's exclusion of non-English speakers and those not enrolled in patient health portals might introduce selection bias, potentially limiting the sample's representativeness.

Strengths

- The study employs a pragmatic trial design, which allows for the evaluation of interventions in real-world clinical settings, enhancing the generalizability of the findings to routine practice.
- Statisticians, investigators, and auditors collecting data are blinded to allocation status, reducing the risk of bias in outcome assessment.
- The study design, including recruitment strategies, align with clinic preferences and involve both routine office visits and population-based identification, providing flexibility and maximizing the potential participant pool.

Introduction

High blood pressure (BP) caused by essential hypertension is one of the most common conditions among adults in the United States (US)[1]. High BP alone rarely has significant symptoms, but sustained high BP, or hypertension, increases risk of heart attack, stroke, heart and kidney failure[2]. The likelihood of adverse cardiovascular outcomes begins to rise at low BP of 115/75 mmHg, and for every twelve-point increase in average BP, the risk doubles [3]. In the US, rates of uncontrolled BP continue to increase, with 46% of adults having Stage 1 (130/80 – 139/89 mmHg) or worse hypertension[1]. Despite advancements in overall health outcomes, BP control has remained poor, with less than half of adults with hypertension meeting a goal of < 140/90 mmHg[1].

Recent studies indicate that effectively managing BP involves navigating a narrow therapeutic window. Overly aggressive treatment increases the risk of significant comorbidities like kidney damage, hypotension, and mood disorders[4]. Evidence suggests that engaging patients directly in intensive goal setting, shared care planning around nonpharmacologic and pharmacologic treatments, and self-monitoring for effectiveness and adverse events reduce risk of cardiovascular events[5]. Appropriately lowering BP without minimizing adverse events is essential for optimizing cardiovascular health and improving patient outcomes. Protocols for BP have remained largely driven by manual decision-making and existing clinical workflows, improving processes but not outcomes. Digital interventions involving Clinical Decision Support (CDS) systems can broaden efforts, but the complexity of high BP has led to mixed successes[6-10]. Hicks et al.[9] showed no significant difference in high BP management using a CDS intervention with providers, while several other CDS trials using multidisciplinary, multifaceted interventions, often including patient engagement and support, have shown reductions in BP and improved control[6, 7, 10, 11].

An essential component of controlling high BP involves empowering patients to manage their condition themselves by regularly monitoring their BP at home and adjusting their approach based on frequent readings. Review of these home data by the patient's health care team is an evidence-based component of hypertension management, but has been historically difficult to integrate into the care team's workflow.[12, 13]

Personalization of BP care plans based on patient needs and experience is also required[12, 14-17]. Patients are encouraged to change health behaviors such as limiting salt intake[18], losing weight[16], stopping smoking[16], adhering to pharmacological treatment plans, and simultaneously self-monitoring for adverse effects. Engaging patients in a process to self-monitor and manage conditions has been extensively studied. Team-based interventions with consistent support for motivation, a focus on self-efficacy, and consideration of affective, or emotional language, may be the key to enhancing engagement.[19] However, uptake is limited, and these approaches are expensive[20]. Digital interventions may be able to provide similar effects, but so far have had less success[21]. This protocol describes a digital intervention study that combines motivational messages with education, counseling, and support to increase patient BP knowledge and self-management capacity[13, 22]. Given our enhanced capability to provide patient-facing CDS[23] and enhanced electronic care planning, integrating CDS thoughtfully into patients' self-management routines is expected to improve their self-efficacy and improve control of chronic illness. Integration requires addressing traditional barriers to CDS integration addressing 5 rights – right person, right format, right time, right channel, and right information – and avoiding reminder fatigue and enhancing motivation with digital interventions.[19]

This intervention is a patient-facing high BP CDS web-based digital tool known as the Collaboration Oriented Application for Controlling High BP (COACH). COACH uses the Fast Healthcare Interoperable Resource (FHIR) standard to incorporate eight extant national and international guidelines[23] into standardized, interoperable CDS and uses the AHRQ Patient-Centered Clinical Decision Support framework[24] to engage patients, caregivers, and care teams in a collaborative implementation process. The trial will implement COACH across multiple clinic sites spanning three major health systems and in the nation's two leading EHR vendor platforms: EPIC and Oracle. Our primary objective is to evaluate the effectiveness of the application at lowering BP via a randomized controlled trial (RCT) comparing two versions of COACH that provide reminders and displays with high affective content (enhanced COACH) versus low affective content (basic COACH) to test improved engagement and results. We will employ a mixed methods design, with qualitative

inquiry nested within the RCT, secondary RE-AIM and social cognitive theory outcomes, and iterative qualitative evaluation of implementations across sites.

COACH was developed with a broad range of patient and clinician viewpoints by: 1) incorporating input from patients and providers throughout the entire lifecycle of CDS[25, 26]; 2) customizing the COACH CDS to align with patient and care team preferences, values, and objectives; and 3) disseminating the open source application and underlying logic. The application is intended to be scalable through standard implementation frameworks, CDS artifacts, and implementation guides[27] that can be adopted beyond this protocol. For interoperability, we use a standard-based, structured process that re-uses concept and value sets from standard terminologies whenever possible while using robust techniques to develop new sets and make them available for future innovators.

Trial Design: The COACH study is a patient randomized multi-site, single-blind, hybrid type III implementation design[28] pragmatic trial leveraging mixed methods[29] using implementation science and informed by Social Cognitive Theory to test the effectiveness of the enhanced COACH application versus basic COACH at lowering BP. The trial plans to enroll 550 participants who will be randomly assigned in a 1:1 ratio to the intervention or the control arm (275 per arm), stratifying by 3 enrollment sites. Outcomes will be collected from home BP measurements entered manually or via Bluetooth link into the COACH application by study participants and via electronic questionnaires completed by participants at baseline, 8 weeks (2 months) and 24 weeks (6 months).

Methods

Pragmatic Design: The pragmatic trial aspects include broad inclusion criteria, no scheduled research visits, tailored workflows within clinic care teams, no clinical staff responsibilities to deliver the intervention, and flexibility in delivery within each site. We employed the PRECIS-2 tool (PRagmatic Explanatory Continuum Indicator Summary) to compare the trial to routine care settings[30]. Figure 1 highlights scores from 9 PRECIS-2 domains, where 1 is explanatory, idealized clinical trial conditions and 5 is pragmatic, closely matching routine care conditions. **Eligibility (5) and Recruitment (4)** All patients with high BP seen in primary care in

the last year will be eligible; these thresholds are standard for determining ongoing home BP monitoring. **Setting (4)** Primary care practices at the participating sites. **Organizational impact (5)** The trial will require no additional staff or modifications to usual care. **Flexible delivery for the practice (5) and adherence for the patient (5)**. The delivery of the application aligns with standard practice for home BP monitoring. The intervention offers initial training for providers to orient them to referral and clinical workflows. **Follow-up (4)** There are no scheduled research visits. Most measurements (clinic encounters, BP data, events, messaging) will be gathered from the electronic health record (EHR). Some additional measures outside usual care (e.g., self-efficacy) will be collected on remotely administered surveys. **Measurement (4)**. Measurements will be part of routine care and the COACH application and will not require additional care team time or effort.

Pre-implementation implementation science evaluation: In preparation for the trial, we conducted a pre-evaluation to explore implementation readiness at each intervention site, including patient perspectives. We utilized a qualitative design and employed patient co-investigators, informed by the Consolidation Framework for Implementation Research (CFIR)[31] domains: Innovation, Outer Setting, Inner Setting, Individual, and Implementation process. Results from this evaluation included dozens of programming and implementation recommendations to improve COACH integration. The research and development teams made programming modifications to the COACH application and applied the implementation recommendations, where possible, to ensure the protocol was pragmatic. Implementation recommendations included referral, intervention design, safety monitoring, integration into care, and ongoing monitoring. Programming changes included more guidance for patients, simpler text, more streamlined workflow and higher contrast display screens.

Patient Involvement: Patient involvement was integral to the development of the COACH clinical trial, as our funded Patient Co-Investigators (Co-Is) actively contributed to incorporating patient preferences. Through focus groups in the pre-implementation phases, patient feedback refined the development process, enhancing the usability of the COACH app and facilitating smoother implementation. Co-Is also played a pivotal role in grant writing, offering essential insights into app usability and priorities. Their involvement extended to building

recruitment materials and enhancing the COACH app. Continuously engaged, they shape plans for disseminating study results to linked communities, ensuring a patient-centered and inclusive approach throughout the study process, from planning dissemination to sharing findings.

Study Setting: Participants are identified from primary care practices associated with three academic health centers (sites) in the United States. The three sites are Oregon Health & Science University (OHSU), University of Missouri-Columbia (MU) and Vanderbilt University Medical Center (VUMC). Participating primary care practices will include Family Medicine and Internal Medicine practices affiliated with each institution.

Eligibility Criteria: Eligible participants are adults aged 18-100 years who communicate in English, receive care at a participating primary care clinic, enrolled in the site's patient health portal and with a visit in the last year. The participant must have elevated BP, defined as a single BP of >140 (>135 home) systolic or >90 (>85 home) diastolic at the current visit or the average of the last 4 BPs is >140 systolic or >90 diastolic, and have a clinician recommendation for a home BP monitoring program. Participants are excluded if they are pregnant at the time of consent, have severe cognitive impairment in the opinion of the clinician, are on hospice care and/or have a life expectancy of less than 2 years, have end-stage renal disease, or for whom tight BP control presents a greater than average risk for falls, dizziness, electrolyte disturbances, hypotension, or active heart failure. Unlike many hypertension trials, we include participants with secondary hypertension as the main objective of COACH is control of hypertension, whatever its cause.

Interventions: Intervention and control groups will have access to the COACH application: intervention will receive enhanced features (Figure 2a), including affective reminders and visualizations, while the control group will receive simpler displays (Figure 2b). All groups will receive safety-related reminders. Reminders include screening, monitoring, self-management goal setting, and prompts to discuss medications (intervention), and significantly high or low BP alerts and suspected adverse events (both groups; see Figure 3). Participants in

both groups receive a validated dual-channel, Bluetooth enabled, home BP monitor (Omron 7 Series® Wireless Upper Arm BP Monitor) with instructions for use.

Outcomes: The **primary** outcome measure is BP control, defined as office < 140/90 or home < 135/85 average of the last set of blood pressures (defined as 12 home or 4 office, whichever are most recent) at 6 months as recorded by participants via home BP measurement and/or at scheduled clinic encounters. Control levels for home and office come from the ACC/AHA guidelines.[5] **Secondary outcomes** include the average reduction in systolic and diastolic BP after 6 months from the initial BP measures at enrollment and changes in key Social Cognitive Theory measures using a health beliefs survey from baseline to 6 months[32, 33]. Technology acceptance and usability will be measured from the Unified Theory of Acceptance and Use of Technology (UTAUT) model[34]. The UTAUT model was developed as an extension of the Technology Acceptance Model and is routinely used in health science research to understand factors associated with successful adoption and sustained use of mHealth interventions. UTAUT domains include performance expectancy (i.e., belief that using the system will be useful or create gains), effort expectancy (i.e., perception that the system is easy to use), social influence (i.e., belief others think they should use the system), and facilitating conditions (i.e., belief there is sufficient organizational and technical support to use the system).

RE-AIM outcomes. As part of the implementation evaluation, we will assess the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) metrics and concepts shown in Table 1. Using the CFIR framework as a guideline, the evaluation will take a mixed methods approach, with iterative cycles of qualitative and quantitative assessments to understand overall implementation successes and challenges. To measure Reach, the total primary care populations from each clinic will be compared to enrolled participants to understand differences in eligible and enrolled populations. Adoption will be measured via the COACH app for both patients and clinicians: log ins, consistent BP tracking, and interaction with the recommendations. For Implementation, semi-structured interviews and a clinician survey will be used to understand the barriers and

facilitators of using COACH in practice. Finally, Maintenance will assess the sustainability of the application through semi-structured interviews.

Participant Timeline: Procedures for the study are in Table 2. Consent is obtained through a REDCap e-consent module, and patient training is completed online with support by phone and email. Once enrolled and randomized, patients are placed in the monitoring block for 4 weeks or until they have 12 BPs. Reminders are provided through the monitoring block, with augmented reminders for the intervention arm. Once the monitoring block is over, patients are prompted to reflect on goals, including contacting their care team. This cycle repeats for up to 6 months. Patient surveys occur at baseline, week 8, and week 24; adverse event survey links are constantly available.

Sample Size and Power: The number of participants we plan to enroll and randomize is 550 across all three sites. We anticipate 40% of participants will come from OHSU (n=225), 40% from MU (n=225), and 20% (n=100) from VUMC. Actual enrollment may differ, and enrollment will continue until 550 participants are randomized.

Total sample size was determined based on a test of two independent proportions (percent with controlled BP at end of trial) assuming level of significance equal to 0.05 (two-sided) and power equal to 90%. We anticipate the intervention arm will increase from 0% controlled at baseline to 40% at 6 months while the control arm will increase from 0% to 25%. Under these assumptions, 406 evaluable participants are required, meaning those with complete data at the 6-month time point. We increased the total enrollment projection to account for attrition and/or uncertainty in projected changes.

Recruitment: Recruitment will take place at primary care practices affiliated with the three sites via two methods: population-based identification using registries and visit-based identification. Consistent with our

pragmatic approach, individual sites and practices can prioritize the recruitment method that best suits their environment and resources. Target recruitment period is from January 2024 to June 2025.

Recruitment mechanisms:

1) Routine office visit (primary): Clinicians will identify a potential participant during a routine office visit where the patient's BP would prompt pharmacologic treatment according to the ACA/AHA guidelines. The clinician can recommend home BP monitoring and initiate a standard patient portal recruitment message with information and links to complete screening, consent and enrollment.

2) Population-based recruitment: Clinicians or team members identify empaneled, active individuals with high BP through an EHR-based report. The responsible clinician or authorized care team member will send patient portal messages in bulk to a set of selected patients, informing them of the study and providing links to complete screening, consent and enrollment. Population-based chronic condition identification and management are employed to varying degrees at each of our study sites.

Methods: Assignment of Interventions

Enrollment After receiving an invitation to participate, patients are directed to a REDCap survey for study information. The patient reviews an information sheet, then gives permission for a research member to contact them and begins the eligibility screening process, as defined above. Eligible participants must give informed consent using an electronic form in REDCap, then proceeds to the baseline survey.

Randomization Upon enrollment and after completing the baseline survey, participants are randomized with a stratification by site to the COACH enhanced intervention arm or COACH basic control arm by central coordinating team at OHSU using the randomization tool in REDCap. The randomization scheme is stratified

by study site, and implemented using a blocking strategy to ensure equal numbers of participants assigned to intervention and control arms within each site.

Allocation- concealment mechanism: The automated randomization system in REDCap can obfuscate the allocation of all patients, and – other than stratification by site – does not depend on time or previous allocation.

Blinding (masking): Statisticians, investigators and auditors collecting BP data from the EHR will be blinded to allocation status. Study participants will be told that the study is testing a home BP monitoring program's effectiveness, but not that it is comparing two care models. Clinicians and care team members will see the enhanced (or intervention) version of COACH. Patients will not be blinded since the COACH display is different for each arm. Once the trial is over, analysts will be provided data with obfuscated study arm.

Methods: Data Collection, management, and analysis

Data collection: We will use several techniques to gather data. First, COACH itself will gather data through FHIR connections to the EHR, pulling all relevant clinical information about the patient. COACH will track home BPs received through manual entry and electronic connections to the Omron mobile application. COACH will also store key information about use, including logins and interaction with recommendations. Second, all surveys will be captured through REDCap hosted at OHSU[33, 35]. REDCap is a secure, broadly used research survey tool that has been integrated with COACH. Standard surveys include the Health Belief Survey; Digital[36] and Health Literacy[37]; and a modified UTAUT survey focused on COACH; schedule is provided in table 2. Patient demographic collection and adverse events will be collected via REDCap. Finally, as part of implementation evaluation, we will gather qualitative data through clinic site visits, observation, focus groups, and interviews; these data will be recorded, and transcribed verbatim.

Data management: All tools used in the study have secure access to the underlying data with auditing capabilities for use; in this secure network, we will store all versions of the study data, and manage secure storage. In addition to extracting data directly from the EHR, patients will enter their self-reported data. For qualitative transcripts, the original recordings will be kept until study completion.

Qualitative data collection: During the implementation and trial, we will conduct bi-monthly video calls with implementation sites. Implementation site-identified stakeholders and champions will be the participants on the calls. We will use a template approach to guiding the call to ensure coverage of relevant topics, altering the template for the stage of implementation and known/evolving context and concerns. We will encourage call participants to voice unique concerns, allowing us to monitor implementation progress, identify barriers, troubleshoot problems, and identify any new and unexpected uses of the tool, including both adverse and beneficial outcomes.

Statistical methods & 20b and c:

Quantitative analysis. The intervention effect on the primary outcome of BP control will be tested using logistic regression model[38] with a binary variable for intervention arm and health system as a categorical variable[39], adjusting for baseline BP, as defined above[40]. Rates of control in each arm and treatment differences will be calculated using mean predicted probabilities from the logistic model[41]. Because randomization is stratified by site, we will include this as a categorical variable for accurate variance estimates and will also adjust for baseline BP. Estimates of the probability of control in each arm and treatment differences will be calculated using mean predicted probabilities from the logistic model.

The secondary outcomes of reduction in systolic and diastolic BP after 6 months will be evaluated with a model sometimes described as constrained longitudinal data analysis (cLDA), in which the two time points are treated as panel data with an observation for each. The model will include a term for time (baseline/final) and an

interaction term for study arm, which constrains the arms to the same baseline mean as expected in a randomized trial but estimates different changes over time. A random effect for patient will be included for the correlation between baseline/final measurements. This model is statistically efficient and accommodates missing measurements, so is a good fit for the intention-to-treat approach.

Continuous secondary outcomes, such as reduction in systolic and diastolic BP after 6 months, will be evaluated with a mixed-effects regression model[38] in which the baseline and 6-month time points are treated as panel data with an observation for each. This model includes a term for time (baseline/final) and an interaction term for study arm. Baseline means are thus constrained to be equal as expected in a randomized trial but changes over time differ. A random effect for patients will model the correlation between baseline/final measurements. This model is statistically efficient and accommodates missing measurements. No adjustments for multiplicity are planned because outcomes are pre-specified and correlated.

Adherence: Participants will be included in analysis once the application and/or home BP monitoring once randomized. Their use of the application will be encouraged by the intervention, but analysis will not depend on their use.

Qualitative analysis. After all site visits are complete, we will arrange transcription of audio using Rev.com. All recorded interviews will be transcribed, verbatim and deidentified for qualitative analysis using the web-based analysis software Dedoose v9[42]. Investigators will create case memos with the CFIR construct ratings for each site across all three health systems and identify CFIR constructs most relevant to the planned implementation across all sites. We will use the method described by Damschroeder and Lowery[43]: 1) assign each site transcript to a pair of analysts who will each independently code the transcripts using the CFIR framework as a coding template with a deductive qualitative analytical approach, 2) develop/build-on case memo for each site, 3) large group discussion with investigators, 4) refine case memo, 5) large group assigns construct ratings, 6) case memo with construct ratings. In step 5, the large group will come to consensus on CFIR construct ratings and score each case/clinic on the identified constructs. It is conventional to rate each

CFIR construct from -2 (strong negative influence on implementation) to +2 (strong positive influence implementation), including 0 (neutral influence on implementation). This process will result in a high-level summary matrix of clinic implementation sites rated on multiple CFIR domains representing positive and negative influences of implementation influences across the 3 health systems[44].

Data from bi-monthly implementation calls will be analyzed in the same manner and will be added to our existing pre-implementation CFIR case memos to provide a rich description of the course of the implementation in each context, allowing comparison across sites, giving insights into both common themes across sites and context-specific differences. This robust synthesis and comparison of experiences across sites and EHR platforms will provide valuable system-level information to inform new implementations, emphasizing common experiences and highlighting relevant context-specific facilitators and barriers. In addition to traditional publication of findings, we will leverage the affiliations of our advisory group and the AHRQ CDS Connect Community as outlets for dissemination.

Data monitoring: The Principal Investigators (PI) will be responsible for ensuring participants' safety on a daily basis. In addition, the study has an empaneled a 12-member Advisory Board composed of national experts, including patient experts, to act as a Data and Safety Monitoring Board (DSMB) and to evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome. The DSMB will make recommendations to the funder and the PIs concerning the continuation, modification, or conclusion of the trial. The DSMB will review the informed consent and make recommendations on any changes to protocol. During the 18-month trial period, the DSMB will meet each quarter to review these data.

Harms: We used the SPRINT trial[4] adverse events (hypotension, dizziness, ED visits, acute kidney injury) for our study adverse events and provide an alert for when these are detected in the EHR to the study team, the patient, and the care team. Risks to participants include: 1) known adverse events from increased treatment and lowered BP, 2) psychological harm, and 3) loss of confidentiality. The adverse events are those common with medical and non-medical treatment of high BP and will be monitored by their primary care clinician.

Auditing: This study uses a single IRB through the University of Missouri-Columbia with reliance from OHSU and VUMC IRBs.

Discussion

The Collaboration Oriented Approach to Controlling High BP (COACH) trial intends to understand how BP control can be improved by increasing adherence to patient-facing guideline-based recommendations. The focus of the trial is on home BP monitoring, as the starting recommendation underscores the key aspect of home-based efforts to assess and self-manage BP. The intervention also "closes the loop" between patient home monitoring, getting patient data to the care team in a way that provides actionable information for hypertension management designed to fit care team preferred workflows and management goals. The intervention, an enhanced version of COACH that includes BP data visualization, affectively enhanced visual summaries, and reminders about BP management, is based on core principles of Social Cognitive Theory, including self-efficacy, social support, outcome expectations, and self-regulation. The underlying premise is that higher affective alerting will increase accuracy in judgments about hypertension control and risk perception and motivate patients out of goal range to appropriate action, without creating excess anxiety, which will allow safe, efficient and effective behavioral and medication changes.

There have been several other trials that address home BP monitoring. Bosworth et al.[45, 46] showed nurse-based telephone support coupled with home BP monitoring was more effective for BP control than usual care or telephone support alone. This effect was strongest for non-white patients. However, individual team-based coaching support is expensive and challenging to scale. Mobile health applications have shown promise in providing this support for key populations, including those with high BP, showing a -4.1 mmHg drop in SBP in a systematic review[20]. These trials generally depend on revised systems of care to enhance patient engagement, with the digital tool a part of the overall intervention COACH is designed to be a scalable electronic patient- and care team-facing intervention that does not require additional personnel to implement.

This trial intends to test whether a more advanced, tailored digital intervention can overcome these barriers in a pragmatic way – in essence, with minimal care redesign. To accomplish the goal, we leverage **Social Cognitive Theory (SCT)** to drive improved patient engagement to measure BPs and accomplish goals for BP lowering. SCT identifies four key mediators of behavior and behavior change: 1) self-efficacy, 2) social support, 3) outcome expectations, and 4) self-regulation[32, 47-51]. We incorporate these principles along with tailored messaging informed by decision psychology into the intervention to drive engagement and uptake[32, 52-54].

We also adapted the trial design based on substantial pre-implementation evaluation. To increase the likelihood of generalizable evidence from the trial, we performed a multimodal qualitative study. Results from the analysis were used to: 1) offer ad hoc and population-based referral techniques that matched high BP quality improvement initiatives in the practices; 2) change the intervention itself to ensure care teams were getting the information they needed; 3) identify additional personnel that participate in BP management, including pharmacists, panel coordinators, and medical assistants; and 4) ensure we had good bi-directional communication with the practices. Our implementation blueprint incorporates these elements and will be useful for researchers looking to implement studies that interdigitate with clinic workflow and minimize burden while maximizing benefit.

This trial is timely. Information exchange standards and regulations are advancing our ability to create highly functional digital interventions that can integrate directly into care. The 21st Century Cures Act and related regulations require healthcare organizations to release information to patients using relevant standards without extra effort. The COACH tool uses these standards (FHIR) to build a comprehensive and tailored tool that can incorporate specific patient context, overcoming previous gaps and enabling easier guidance. Our previous work showed that the available data through the EHR FHIR server was not sufficient to use standard guideline recommendations without adaptations needed to consider missing and inaccurate data;[24] these adaptations may help expand available data since we are exchanging data back to the EHR.

The results of this trial will help to understand how engagement with digital interventions can be enhanced with affective alerts and other design changes; and whether these changes can help lower blood pressure in a pragmatic way through home monitoring. The flexibility of the tool, its adherence to standards, and incorporation into a carefully designed implementation blueprint to fit into workflow will be helpful to future researchers and innovators. In addition, the explicit goal of placing minimal burden on care teams and engaging patients in achieving safe and effective BP control is likely to generate knowledge useful about how to optimally redesign primary care processes.

Ethics and Dissemination

Research ethics approval: Single IRB oversight though the University of Missouri-Columbia IRB, #2091483.

Protocol amendments: Key Study Personnel (KSP) plan to communicate important protocol modifications (e.g, changes to eligibility criteria, outcomes, analyses) to the appropriate parties (e.g, IRB, trial participants, DSMB).

Consent and assent: KSP will obtain informed consent from potential trial participants through an electronic tool called REDCap.

Confidentiality: The Principal Investigators (PI) will be responsible for ensuring participants' privacy, confidentiality and data security. Data collection via REDCap will enhance data security. All data will be stored on secure encrypted, HIPAA compliant, SharePoint/OneDrive securely. COACH access has been strategically nested within the 3 sites' EHRs/patient portals to eliminate additional sign-ons and exposure to data threats. The

Data and Safety Monitoring Board (DSMB) will review any instances of loss of confidentiality and will review adverse events that meet the reporting requirements. The DSMB will make recommendations to AHRQ and the PIs concerning the continuation, modification, or conclusion of the trial.

Declaration of interests: The PIs have complete control over trial design and analysis. Besides funding from AHRQ, no other potential conflicts of interest exist.

Access to data: KSP have registered this trial on Clinicaltrials.gov identifier number: NCT06124716.

Ancillary and post-trial care: Care will always be directed by the care team, and the use of the tool or similar functions will be available after the trial is over.

Dissemination policy: Trial results and the implementation details, including the logic and concepts from COACH, will be made available via publications, on Clinicaltrials.gov, and via open source mechanisms[27, 55].

Authorship eligibility guidelines: ICJME guidelines will be used for authorship.

Public access: Trial results will be available at clinicaltrials.gov and the intervention details will be provided in a complete Implementation Guide as an open-source resource on GitHub.

Appendices

Appendix 1. COACH Consortium authors
Appendix 2. SPIRIT Checklist
Appendix 3. Informed consent materials

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Table 1. RE-AIM measures and outcomes

RE-AIM Evaluation Measures		
Component	**Outcome Measures**	**Source**
Reach		
1. Number of eligible enrolled patients	CONSORT	REDCap - baseline survey
2. Differences from the eligible population	CONSORT	REDCap - baseline survey
Effectiveness		
1. Intervention effects on outcome	Primary	Electronic Health Record, patient portal
	Secondary	Electronic Health Record, patient portal
2. Increase in patient:	Social Cognitive Theory	Patient 2/6 month follow up survey
Adoption		
1. Number of Home BP recordings entered	Counts	Electronic Health Record, patient portal
2. Number of encountered study blocks	App usage	Electronic Health Record, patient portal
Implementation		
1. Number of portal/phone messages about BP during 6-month intervention period		Electronic Health Record, patient portal
2. Barriers to Implementation	Interviews	CFIR Evaluation
3. Increased/decreased burden of intervention	Interviews	CFIR Evaluation
4. physician/nurse/patient suggestions	Interviews	CFIR Evaluation
5. participant support needs	Email, phone outreach to study staff	REDCap ongoing events
Maintenance		
1. Number of patients who continue to use the app and BP cuff		Study Participant Tracking
2. Institutional use of tools beyond trial		CFIR Evaluation

Table 2. COACH Study Visit Schedule

Procedure	Baseline	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8	Week 24
Information Sheet, Consent, Screening, randomization	X							
Receive COACH related Instructions/materials	X							
Monitoring Block (2-4 Weeks)			If Needed post 2 weeks					
Goal Setting Block (1-2 Weeks)			If Monitoring block ends in 2 weeks		If monitoring block ends in more than 2 weeks			
Health Belief Survey	X							
Digital and Health Literacy	X							
UTAUT							X	X
REDCap Alerts								
REDCap Alerts (Control)								
AE Form*							X	X

*AE form continuously available

Figure 1. PRECIS-2 Diagram

228x192mm (47 x 47 DPI)

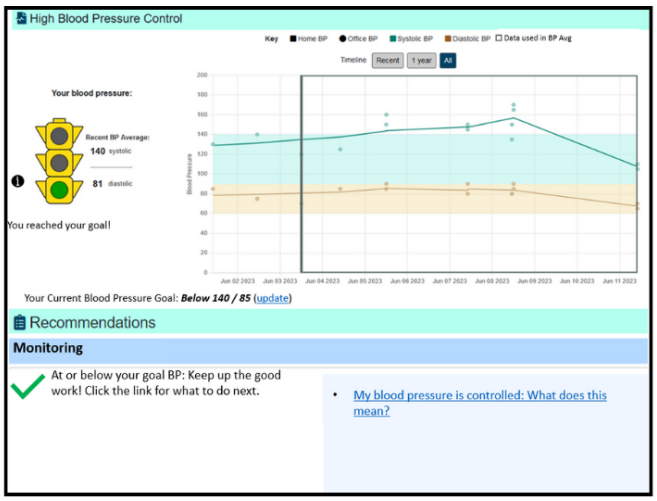

Figure 2a: Home page for enhanced arm COACH

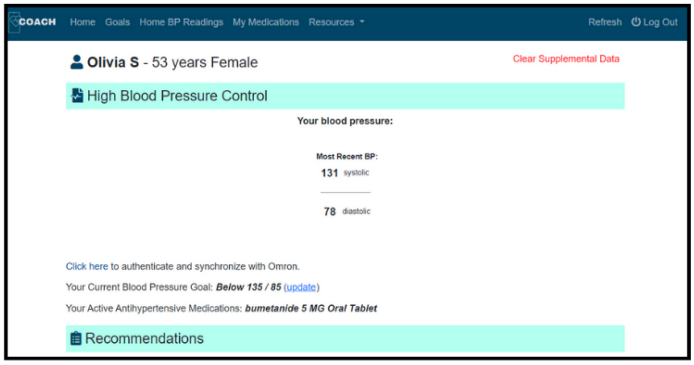

Figure 2b: Home page for control arm COACH

Figure 2a: Home page for enhanced arm COACH
Figure 2b: Home page for control arm COACH

721x721mm (38 x 38 DPI)

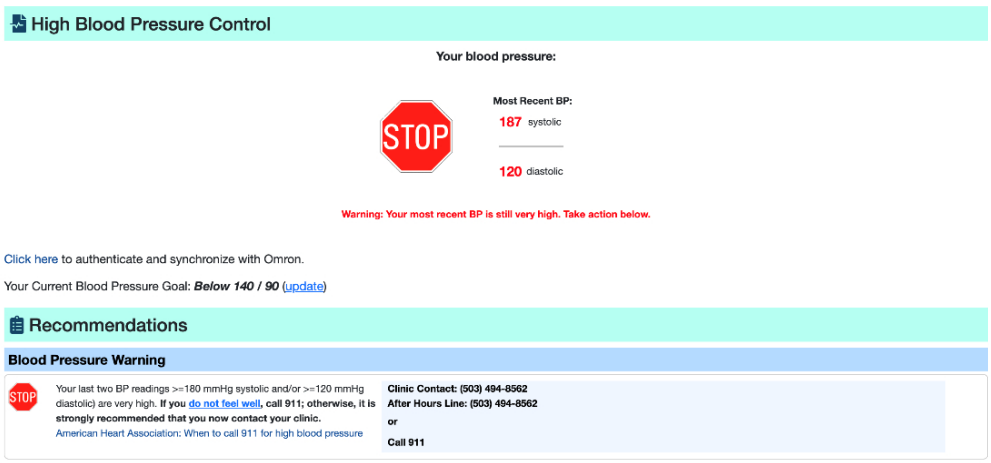

Figure 3: High BP warning (similar for low BP) for both groups

321x150mm (87 x 87 DPI)

Appendix 1: COACH Consortium

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
	6b	Explanation for choice of comparators	n/a
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	15
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	17
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	18
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	18
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

IRB # STUDY00024520

CLINICAL RESEARCH CONSENT AND AUTHORIZATION
SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Collaboration Oriented Approach to Controlling High Blood Pressure (COACH)

PRINCIPAL INVESTIGATORS: Richelle Koopman, MD, MS (573) 882-0598
David Dorr, MD, MS (503) 418-2387

CO-INVESTIGATOR: William Martinez, MD, MSc (615) 322-3000

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not. This is a multi-site study with University of Missouri-Columbia (MU), Oregon Health & Sciences University (OHSU) and Vanderbilt University Medical Center (VUMC).

PURPOSE: The purpose of the study is to learn how well the COACH application can help lower blood pressure. We are hoping to find out ways to help people manage high blood pressure.

DURATION: Your participation in the study will consist of three surveys over 6 months and blood pressure monitoring from home. Surveys will last up to 20 minutes each.

PROCEDURES: If you decide to participate, you will be asked to complete surveys now, in 8 weeks and in 6 months. You will also be asked to use the COACH application and to monitor your blood pressure during those 6 months.

RISKS: The main risk is a loss of confidentiality. You may also feel side effects that are common during blood pressure management.

BENEFITS: You may not directly benefit from taking part in this research. The COACH application may help you reduce your blood pressure.

ALTERNATIVES: You may choose not to participate in this study, may receive standard blood pressure treatment or participate in another study if one is available.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Study Team if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

IRB # STUDY00024520

Research Consent and Authorization Form

PROJECT TITLE: Collaboration Oriented Approach to Controlling High Blood Pressure (COACH)

PRINCIPAL INVESTIGATORS: Richelle Koopman, MD, MS (573) 882-0598
David Dorr, MD, MS (503) 418-2387

CO-INVESTIGATOR: William Martinez, MD, MSc (615) 322-3000

This is a multi-site study with University of Missouri- Columbia (MU), Oregon Health & Sciences University (OHSU) and Vanderbilt University Medical Center (VUMC).

CONTACT INFORMATION:

Email: COACH-OHSU@ohsu.edu
Phone: 833-462-9191

WHO IS PAYING FOR THE STUDY? *Agency for Healthcare Research and Quality (AHRQ)*

WHO IS PROVIDING SUPPORT FOR THE STUDY? *None*

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY? *No*

WHY IS THIS STUDY BEING DONE?

You have been invited to be in this research study because you have high blood pressure and your clinician or care team recommend that you participate in a home blood pressure monitoring program. The purpose of this study is to evaluate the effectiveness of the COACH application to lower blood pressure using evidence-based research and patient participation to maximize effectiveness.

A total of 550 patients will be enrolled into the study. Patients are asked to participate in this study for 6 months. You will be asked to monitor your blood pressure using the COACH application and complete surveys.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

In addition to your regular blood pressure management regiment, you will use the COACH web-based application to measure your blood pressure regularly. You will be provided a link that directs you to instructions on how to use the COACH application. You will be asked to measure your blood pressure regularly from your home. We will provide you with a blood pressure cuff with Bluetooth connection to use at home and record your results in COACH. You will receive information about your blood pressure readings and may receive additional recommendations. Your health record information including medications and blood pressure will be accessed by COACH.

You will complete surveys at three time points. The surveys will ask questions about how you manage your health and your experience using the COACH application.

Below is a breakdown of study procedures you may expect to complete as a participant in this study:

	Baseline Day 1	Week 8 (2 months)	Week 24 (6 months)
Consent Discussion, Screening questions and Survey #1	X		
Receive information on how to use COACH	X		
Survey #2		X	
Survey #3			X
Study payment for completing survey #3			X
Total time	30-60 minutes	20-25 minutes	20-25 minutes

WILL I RECEIVE RESULTS FROM THE STUDY?

You will not receive results from this study. However, your care team will be notified when your blood pressure is high (>180mmHg/120mmHg) or low (<90mmHg/60mmHg).

If you are interested in staying informed about the progress being made on the development of the application, and continuing to contribute to the development process, we may ask for your permission to contact you again in the future.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. You may also experience some side effects commonly experienced when people manage their blood pressure could include dizziness.

PERMISSION TO USE YOUR PROTECTED HEALTH INFORMATION:

State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.

You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

In this study we will take steps to keep your personal information confidential, but we cannot guarantee total privacy. We will be deidentifying information for data analysis.

Some identifiers about you will be obtained from your health records and are necessary for this research. The identifiers will include your name, address, dates related to you, phone numbers, email addresses, medical record number, social security number.

We may have to release this information to others for example, if the study is audited. However, we would try to do so without information that could identify you. This release could be to the Institutional Review Board (ethics review committee) overseeing the study at the University of Missouri, the Agency for Healthcare Research and Quality, or Office of Human Research Protection (agencies that oversee research). Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.

We may continue to use and disclose your information as described above indefinitely to disseminate research findings and results.

Some of the information collected and created in this study may be placed in your medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your medical record. If you have questions about what study information you will be able to access, and when, ask the study team.

After you join the study, you can choose to receive all future survey links and reminders by text message. If you choose this option, you are giving us permission to share your phone number with our vendor Twilio Inc. to send you these text messages.

We will limit the content of the text messages to general information such as survey links and reminders to complete your survey. Even so, these messages may contain information that you wish to keep confidential. Text messaging is not encrypted, messages can be intercepted by others, viewed by people who see your phone or sent to the wrong person, and may not be confidential.

If, at any point, you no longer wish to receive text messages from the study team, tell us by sending an email to COACH-OHSU@ohsu.edu or calling this number 1-833-462-9191, and we will stop sending you text messages.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no cost to you or your insurance company to participate in this study. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your medical condition. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

If you remain in the study and complete the final survey at 24 weeks (6 months), you will receive a $20 payment via electronic gift card. The gift card will be delivered via email and you will have an option to choose between Amazon, Walmart or Target.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact **COACH-OHSU@ohsu.edu**.

If you are injured or harmed by the study procedures, you will be treated. Any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

WHERE CAN I GET MORE INFORMATION?

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Richelle Koopman at koopmanr@health.missouri.edu or other members of the study team at COACH-OHSU@ohsu.edu. or call 833-462-9191.

If you have questions about your rights as a research participant, please contact the MU Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?

As a participant in this study we will ask you to monitor you blood pressure regularly and record it in the COACH application. We will also ask you to complete surveys at three time points during the study.

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the study team if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

COACH Coordinator: COACH-OHSU@ohsu.edu (one email for all 3 sites)

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

The information that we will collect from you will not be stored with your name or any other identifier. Therefore, there will not be a way for us to identify and destroy your materials if you decide in the future that you do not wish to participate in this research.

You may be removed from the study if the investigator or funder stops the study, your primary care provider believes it is not safe for you to continue with the study, or if you meet the exclusion criteria after signing this consent document.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study. We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

BMJ Open

Study Protocol: Collaboration Oriented Approach to Controlling High blood pressure (COACH) in adults - A Randomized Controlled Trial

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Title: Study Protocol: Collaboration Oriented Approach to Controlling High blood pressure (COACH) in adults - A Randomized Controlled Trial

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Abstract

Introduction Hypertension, the clinical condition of persistent high blood pressure (BP), is preventable yet remains a significant contributor to poor cardiovascular outcomes. Digital self-management support tools can increase patient self-care behaviors to improve BP. We created a patient- and provider-facing clinical decision support (CDS) application, called the Collaboration Oriented Approach to Controlling High BP (COACH), to integrate home BP data, guideline recommendations, and patient-centered goals with primary care workflows. We leverage Social Cognitive Theory principles to support enhanced engagement, shared decision-making, and self-management support. This study aims to measure the effectiveness of the COACH intervention and evaluate its adoption as part of BP management.

Methods and analysis. Study design is a **multi-site,** two-arm hybrid Type III implementation randomized controlled trial set within primary care practices across three health systems. Randomized participants are adults with high BP for whom home BP monitoring is indicated. The intervention arm will receive COACH, a digital we based intervention with **affectively enhanced** alerts and displays intended to drive engagement with BP lowering; the control arm will receive COACH without the alerts and a simple display. Outcome measures include BP lowering (primary) and self-efficacy (secondary). Implementation pre-planning and post-evaluation uses the Consolidated Framework for Implementation Research and RE-AIM metrics with iterative cycles for qualitative integration into the trial and its quantitative evaluation. Trial analysis includes logistic regression and constrained longitudinal data analysis.

Ethics and Dissemination. The trial is approved under a single IRB through the University of Missouri-Columbia, #2091483. Dissemination of the intervention specifications and results will be through open-source mechanisms.

Strengths and limitations of this study

Limitations

- The study's utilization of participants solely from three academic health centers in the United States might restrict the applicability of the results to wider demographics.

- The eligibility criteria's exclusion of non-English speakers and those not enrolled in patient health portals might introduce selection bias, potentially limiting the sample's representativeness.

Strengths

- The study employs a pragmatic trial design, which allows for the evaluation of interventions in real-world clinical settings, enhancing the generalizability of the findings to routine practice.
- Statisticians, investigators, and auditors collecting data are blinded to allocation status, reducing the risk of bias in outcome assessment.
- The study design, including recruitment strategies, aligns with clinic preferences and involves both routine office visits and population-based identification, providing flexibility and maximizing the potential participant pool.

Introduction

High blood pressure (BP) caused by essential hypertension is one of the most common conditions among adults in the United States (US)[1]. High BP alone rarely has significant symptoms, but sustained high BP, or hypertension, increases risk of heart attack, stroke, heart and kidney failure[2]. The likelihood of adverse cardiovascular outcomes begins to rise at low BP of 115/75 mmHg, and for every twelve-point increase in average BP, the risk doubles [3]. In the US, rates of uncontrolled BP continue to increase, with 46% of adults having Stage 1 (130/80 – 139/89 mmHg) or worse hypertension[1]. Despite advancements in overall health outcomes, BP control has remained poor, with less than half of adults with hypertension meeting a goal of < 140/90 mmHg[1].

Recent studies indicate that effectively managing BP involves navigating a narrow therapeutic window. Overly aggressive treatment increases the risk of significant comorbidities like kidney damage, hypotension, and mood disorders[4]. Evidence suggests that engaging patients directly in intensive goal setting, shared care planning around nonpharmacologic and pharmacologic treatments, and self-monitoring for effectiveness and adverse events reduces risk of cardiovascular events[5]. Appropriately lowering BP without minimizing adverse events is essential for optimizing cardiovascular health and improving patient outcomes. Protocols for BP have remained largely driven by manual decision-making and existing clinical workflows, improving processes but not outcomes. Digital interventions involving Clinical Decision Support (CDS) systems can broaden efforts, but the complexity of high BP has led to mixed successes[6-10]. Hicks et al.[9] showed no significant difference in high BP management using a CDS intervention with providers, while several other CDS trials using multidisciplinary, multifaceted interventions, often including patient engagement and support, have shown reductions in BP and improved control[6, 7, 10, 11].

An essential component of controlling high BP involves empowering patients to manage their condition themselves by regularly monitoring their BP at home and adjusting their approach based on frequent readings. Review of these home data by the patient's health care team is an evidence-based component of hypertension management, but has been historically difficult to integrate into the care team's workflow.[12, 13]

Personalization of BP care plans based on patient needs and experience is also required[12, 14-17]. Patients are encouraged to change health behaviors such as limiting salt intake[18], losing weight[16], stopping smoking[16], adhering to pharmacological treatment plans, and simultaneously self-monitoring for adverse effects. Engaging patients in a process to self-monitor and manage conditions has been extensively studied. Team-based interventions with consistent support for motivation, a focus on self-efficacy, and consideration of affective, or emotional language, may be the key to enhancing engagement.[19] However, uptake is limited, and these approaches are expensive[20]. Digital interventions may be able to provide similar effects, but so far have had less success[21]. This protocol describes a digital intervention study that combines motivational messages with education, counseling, and support to increase patient BP knowledge and self-management capacity[13, 22]. Given our enhanced capability to provide patient-facing CDS[23] and enhanced electronic care planning, integrating CDS thoughtfully into patients' self-management routines is expected to improve their self-efficacy and improve control of chronic illness. Integration requires addressing traditional barriers to CDS integration addressing 5 rights – right person, right format, right time, right channel, and right information – and avoiding reminder fatigue and enhancing motivation with digital interventions.[19]

This intervention is a patient-facing high BP CDS web-based digital tool known as the Collaboration Oriented Application for Controlling High BP (COACH). COACH uses the Fast Healthcare Interoperable Resource (FHIR) standard to incorporate eight extant national and international guidelines[23] into standardized, interoperable CDS and uses the AHRQ Patient-Centered Clinical Decision Support framework[24] to engage patients, caregivers, and care teams in a collaborative implementation process. The trial will implement COACH across multiple clinic sites spanning three major health systems and in the nation's two leading EHR vendor platforms: EPIC and Oracle. Our primary objective is to evaluate the effectiveness of the application at lowering BP via a randomized controlled trial (RCT) comparing two versions of COACH that provide reminders and displays with high affective content (enhanced COACH) versus low affective content (basic COACH) to test improved engagement and results. We will employ a mixed methods design, with qualitative

inquiry nested within the RCT, secondary RE-AIM and social cognitive theory outcomes, and iterative qualitative evaluation of implementations across sites.

COACH was developed with a broad range of patient and clinician viewpoints by: 1) incorporating input from patients and providers throughout the entire lifecycle of CDS[25, 26]; 2) customizing the COACH CDS to align with patient and care team preferences, values, and objectives; and 3) disseminating the open source application and underlying logic. The application is intended to be scalable through standard implementation frameworks, CDS artifacts, and implementation guides[27] that can be adopted beyond this protocol. For interoperability, we use a standard-based, structured process that re-uses concept and value sets from standard terminologies whenever possible while using robust techniques to develop new sets and make them available for future innovators.

Trial Design: The COACH study is a patient randomized multi-site, single-blind, hybrid type III implementation design[28] pragmatic trial leveraging mixed methods[29] using implementation science and informed by Social Cognitive Theory to test the effectiveness of the enhanced COACH application versus basic COACH at lowering BP. The trial plans to enroll 550 participants who will be randomly assigned in a 1:1 ratio to the intervention or the control arm (275 per arm), stratifying by 3 enrollment sites. Outcomes will be collected from home BP measurements entered manually or via Bluetooth link into the COACH application by study participants and via electronic questionnaires completed by participants at baseline, 8 weeks (2 months) and 24 weeks (6 months).

Methods

Pragmatic Design: The pragmatic trial aspects include broad inclusion criteria, no scheduled research visits, tailored workflows within clinic care teams, no clinical staff responsibilities to deliver the intervention, and flexibility in delivery within each site. We employed the PRECIS-2 tool (PRagmatic Explanatory Continuum Indicator Summary) to compare the trial to routine care settings[30]. Figure 1 highlights scores from 9 PRECIS-2 domains, where 1 is explanatory, idealized clinical trial conditions and 5 is pragmatic, closely matching routine care conditions. **Eligibility (5) and Recruitment (4)** All patients with high BP seen in primary care in

the last year will be eligible; these thresholds are standard for determining ongoing home BP monitoring. **Setting (4)** Primary care practices at the participating sites. **Organizational impact (5)** The trial will require no additional staff or modifications to usual care. **Flexible delivery for the practice (5) and adherence for the patient (5)**. The delivery of the application aligns with standard practice for home BP monitoring. The intervention offers initial training for providers to orient them to referral and clinical workflows. **Follow-up (4)** There are no scheduled research visits. Most measurements (clinic encounters, BP data, events, messaging) will be gathered from the electronic health record (EHR). Some additional measures outside usual care (e.g., self-efficacy) will be collected on remotely administered surveys. **Measurement (4)**. Measurements will be part of routine care and the COACH application and will not require additional care team time or effort.

Pre-implementation implementation science evaluation: In preparation for the trial, we conducted a pre-evaluation to explore implementation readiness at each intervention site, including patient perspectives (See Appendix 1 and 2). We utilized a qualitative design and employed patient co-investigators, informed by the Consolidation Framework for Implementation Research (CFIR)[31] domains: Innovation, Outer Setting, Inner Setting, Individual, and Implementation process. Results from this evaluation included dozens of programming and implementation recommendations to improve COACH integration. The research and development teams made programming modifications to the COACH application and applied the implementation recommendations, where possible, to ensure the protocol was pragmatic. Implementation recommendations included referral, intervention design, safety monitoring, integration into care, and ongoing monitoring. Programming changes included more guidance for patients, simpler text, more streamlined workflow and higher contrast display screens.

Patient Involvement: Patient involvement was integral to the development of the COACH clinical trial, as our funded Patient Co-Investigators (Co-Is) actively contributed to incorporating patient preferences. Through focus groups in the pre-implementation phases, patient feedback refined the development process, enhancing the usability of the COACH app and facilitating smoother implementation. Co-Is also played a pivotal role in grant

writing, offering essential insights into app usability and priorities. Their involvement extended to building recruitment materials and enhancing the COACH app. Continuously engaged, they shape plans for disseminating study results to linked communities, ensuring a patient-centered and inclusive approach throughout the study process, from planning dissemination to sharing findings.

Study Setting: Participants are identified from primary care practices associated with three academic health centers (sites) in the United States. The three sites are Oregon Health & Science University (OHSU), University of Missouri-Columbia (MU) and Vanderbilt University Medical Center (VUMC). Participating primary care practices will include Family Medicine and Internal Medicine practices affiliated with each institution. Funding for the study spans from July 2022 to June 2025, with enrollment scheduled to begin in January 2024.

Eligibility Criteria: Eligible participants are adults aged 18-100 years who communicate in English, receive care at a participating primary care clinic, enrolled in the site's patient health portal and with a visit in the last year. The participant must have elevated BP, defined as a single BP of >140 (>135 home) systolic or >90 (>85 home) diastolic at the current visit or the average of the last 4 BPs is >140 systolic or >90 diastolic, and have a clinician recommendation for a home BP monitoring program. Participants are excluded if they are pregnant at the time of consent, have severe cognitive impairment in the opinion of the clinician, are on hospice care and/or have a life expectancy of less than 2 years, have end-stage renal disease, or for whom tight BP control presents a greater than average risk for falls, dizziness, electrolyte disturbances, hypotension, or active heart failure. COACH includes participants with secondary hypertension as the main objective is to control hypertension, no matter what the cause.

Interventions: Intervention and control groups will have access to the COACH application: intervention will receive enhanced features (Figure 2a), including affective reminders and visualizations, while the control group will receive simpler displays (Figure 2b). All groups will receive safety-related reminders. Reminders include

screening, monitoring, self-management goal setting, and prompts to discuss medications (intervention), and significantly high or low BP alerts and suspected adverse events (both groups; see Figure 3). Participants in both groups receive a validated dual-channel, Bluetooth enabled, home BP monitor (Omron 7 Series® Wireless Upper Arm BP Monitor) with instructions for use.

Outcomes: The **primary** outcome measure is BP control, defined as office < 140/90 or home < 135/85 average of the last set of blood pressures (defined as 12 home or 4 office, whichever are most recent) at 6 months as recorded by participants via home BP measurement and/or at scheduled clinic encounters. Control levels for home and office come from the ACC/AHA guidelines.[5] **Secondary outcomes** include the average reduction in systolic and diastolic BP after 6 months from the initial BP measures at enrollment and changes in key Social Cognitive Theory measures using a health beliefs survey from baseline to 6 months[32, 33]. Technology acceptance and usability will be measured from the Unified Theory of Acceptance and Use of Technology (UTAUT) model[34]. The UTAUT model was developed as an extension of the Technology Acceptance Model and is routinely used in health science research to understand factors associated with successful adoption and sustained use of mHealth interventions. UTAUT domains include performance expectancy (i.e., belief that using the system will be useful or create gains), effort expectancy (i.e., perception that the system is easy to use), social influence (i.e., belief others think they should use the system), and facilitating conditions (i.e., belief there is sufficient organizational and technical support to use the system).

RE-AIM outcomes. As part of the implementation evaluation, we will assess the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) metrics and concepts shown in Table 1. Using the CFIR framework as a guideline, the evaluation will take a mixed methods approach, with iterative cycles of qualitative and quantitative assessments to understand overall implementation successes and challenges. To measure Reach, the total primary care populations from each clinic will be compared to enrolled participants to understand differences in eligible and enrolled populations. Adoption will be measured via the COACH app for both

patients and clinicians: log ins, consistent BP tracking, and interaction with the recommendations. For Implementation, semi-structured interviews and a clinician survey will be used to understand the barriers and facilitators of using COACH in practice. Finally, Maintenance will assess the sustainability of the application through semi-structured interviews.

Participant Timeline: Procedures for the study are in Table 2. Consent is obtained through a REDCap e-consent module, and patient training is completed online with support by phone and email. Once enrolled and randomized, patients are placed in the monitoring block for 4 weeks or until they have 12 BPs. Reminders are provided through the monitoring block, with augmented reminders for the intervention arm. Once the monitoring block is over, patients are prompted to reflect on goals, including contacting their care team. This cycle repeats for up to 6 months. Patient surveys occur at baseline, week 8, and week 24; adverse event survey links are constantly available.

Sample Size and Power: The number of participants we plan to enroll and randomize is 550 across all three sites. We anticipate 40% of participants will come from OHSU (n=225), 40% from MU (n=225), and 20% (n=100) from VUMC. Actual enrollment may differ, and enrollment will continue until 550 participants are randomized.

Total sample size was determined based on a test of two independent proportions (percent with controlled BP at end of trial) assuming level of significance equal to 0.05 (two-sided) and power equal to 90%. We anticipate the intervention arm will increase from 0% controlled at baseline to 40% at 6 months while the control arm will increase from 0% to 25%. Under these assumptions, 406 evaluable participants are required, meaning those with complete data at the 6-month time point. We increased the total enrollment projection to account for attrition and/or uncertainty in projected changes.

Recruitment: Recruitment will take place at primary care practices affiliated with the three sites via two methods: population-based identification using registries and visit-based identification. Consistent with our pragmatic approach, individual sites and practices can prioritize the recruitment method that best suits their environment and resources. Target recruitment period is from January 2024 to June 2025.

Recruitment mechanisms:

1) Routine office visit (primary): Clinicians will identify a potential participant during a routine office visit where the patient's BP would prompt pharmacologic treatment according to the ACA/AHA guidelines. The clinician can recommend home BP monitoring and initiate a standard patient portal recruitment message with information and links to complete screening, consent and enrollment.

2) Population-based recruitment: Clinicians or team members identify empaneled, active individuals with high BP through an EHR-based report. The responsible clinician or authorized care team member will send patient portal messages in bulk to a set of selected patients, informing them of the study and providing links to complete screening, consent and enrollment. Population-based chronic condition identification and management are employed to varying degrees at each of our study sites.

Methods: Assignment of Interventions

Enrollment After receiving an invitation to participate, patients are directed to a REDCap survey for study information. The patient reviews an information sheet, then begin the eligibility screening process, as defined above. Eligible participants must give informed consent (see Appendix 3) by signing an electronic form in REDCap, then proceed to the baseline survey.

Randomization Upon enrollment and after completing the baseline survey, participants are randomized with a stratification by site to the COACH enhanced intervention arm or COACH basic control arm by central coordinating team at OHSU using the randomization tool in REDCap. The randomization scheme is stratified by study site, and implemented using a blocking strategy to ensure equal numbers of participants assigned to intervention and control arms within each site.

Allocation- concealment mechanism: The automated randomization system in REDCap can obfuscate the allocation of all patients, and – other than stratification by site – does not depend on time or previous allocation.

Blinding (masking): Statisticians, investigators and auditors collecting BP data from the EHR will be blinded to allocation status. Study participants will be told that the study is testing a home BP monitoring program's effectiveness, but not that it is comparing two care models. Clinicians and care team members will see the enhanced (or intervention) version of COACH. Patients will not be blinded since the COACH display is different for each arm. Once the trial is over, analysts will be provided data with an obfuscated study arm.

Methods: Data Collection, management, and analysis

Data collection: We will use several techniques to gather data. First, COACH itself will gather data through FHIR connections to the EHR, pulling all relevant clinical information about the patient. COACH will track home BPs received through manual entry and electronic connections to the Omron mobile application. COACH will also store key information about use, including logins and interaction with recommendations. Second, all surveys will be captured through REDCap hosted at OHSU[33, 35]. REDCap is a secure, broadly used research survey tool that has been integrated with COACH. Standard surveys include the Health Belief Survey; Digital[36] and Health Literacy[37]; and a modified UTAUT survey focused on COACH; schedule is provided in Table 2. Patient demographic collection and adverse events will be collected via REDCap. Finally, as part of

implementation evaluation, we will gather qualitative data through clinic site visits, observation, focus groups, and interviews; these data will be recorded, and transcribed verbatim.

Data management: All tools used in the study have secure access to the underlying data with auditing capabilities for use; in this secure network, we will store all versions of the study data, and manage secure storage. In addition to extracting data directly from the EHR, patients will enter their self-reported data. For qualitative transcripts, the original recordings will be kept until study completion.

Qualitative data collection: During the implementation and trial, we will conduct bi-monthly video calls with implementation sites. Implementation site-identified stakeholders and champions will be the participants on the calls. We will use a template approach to guide the call to ensure coverage of relevant topics, altering the template for the stage of implementation and known/evolving context and concerns. We will encourage call participants to voice unique concerns, allowing us to monitor implementation progress, identify barriers, troubleshoot problems, and identify any new and unexpected uses of the tool, including both adverse and beneficial outcomes.

Statistical methods & 20b and c:

Quantitative analysis. The intervention effect on the primary outcome of BP control will be tested using logistic regression model[38] with a binary variable for intervention arm and health system as a categorical variable[39], adjusting for baseline BP, as defined above[40]. Rates of control in each arm and treatment differences will be calculated using mean predicted probabilities from the logistic model[41]. Because randomization is stratified by site, we will include this as a categorical variable for accurate variance estimates and will also adjust for baseline BP. Estimates of the probability of control in each arm and treatment differences will be calculated using mean predicted probabilities from the logistic model.

The secondary outcomes of reduction in systolic and diastolic BP after 6 months will be evaluated with a model sometimes described as constrained longitudinal data analysis (cLDA), in which the two time points are treated as panel data with an observation for each. The model will include a term for time (baseline/final) and an interaction term for study arm, which constrains the arms to the same baseline mean as expected in a randomized trial but estimates different changes over time. A random effect for patient will be included for the correlation between baseline/final measurements. This model is statistically efficient and accommodates missing measurements, so is a good fit for the intention-to-treat approach.

Continuous secondary outcomes, such as reduction in systolic and diastolic BP after 6 months, will be evaluated with a mixed-effects regression model[38] in which the baseline and 6-month time points are treated as panel data with an observation for each. This model includes a term for time (baseline/final) and an interaction term for study arm. Baseline means are thus constrained to be equal as expected in a randomized trial but changes over time differ. A random effect for patients will model the correlation between baseline/final measurements. This model is statistically efficient and accommodates missing measurements. No adjustments for multiplicity are planned because outcomes are pre-specified and correlated.

Adherence: Participants will be included in analysis once the application and/or home BP monitoring once randomized. Their use of the application will be encouraged by the intervention, but analysis will not depend on their use.

Qualitative analysis. After all site visits are complete, we will arrange transcription of audio using Rev.com. All recorded interviews will be transcribed, verbatim and deidentified for qualitative analysis using the web-based analysis software Dedoose v9[42]. Investigators will create case memos with the CFIR construct ratings for each site across all three health systems and identify CFIR constructs most relevant to the planned implementation across all sites. We will use the method described by Damschroeder and Lowery[43]: 1) assign each site transcript to a pair of analysts who will each independently code the transcripts using the CFIR framework as a coding template with a deductive qualitative analytical approach, 2) develop/build-on case

memo for each site, 3) large group discussion with investigators, 4) refine case memo, 5) large group assigns construct ratings, 6) case memo with construct ratings. In step 5, the large group will come to consensus on CFIR construct ratings and score each case/clinic on the identified constructs. It is conventional to rate each CFIR construct from -2 (strong negative influence on implementation) to +2 (strong positive influence implementation), including 0 (neutral influence on implementation). This process will result in a high-level summary matrix of clinic implementation sites rated on multiple CFIR domains representing positive and negative influences of implementation influences across the 3 health systems[44].

Data from bi-monthly implementation calls will be analyzed in the same manner and will be added to our existing pre-implementation CFIR case memos to provide a rich description of the course of the implementation in each context, allowing comparison across sites, giving insights into both common themes across sites and context-specific differences. This robust synthesis and comparison of experiences across sites and EHR platforms will provide valuable system-level information to inform new implementations, emphasizing common experiences and highlighting relevant context-specific facilitators and barriers. In addition to traditional publication of findings, we will leverage the affiliations of our advisory group and the AHRQ CDS Connect Community as outlets for dissemination.

Data monitoring: The Principal Investigators (PI) will be responsible for ensuring participants' safety daily. In addition, the study has an empaneled a 12-member Advisory Board composed of national experts, including patient experts, to act as a Data and Safety Monitoring Board (DSMB) and to evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome. The DSMB will make recommendations to the funder and the PIs concerning the continuation, modification, or conclusion of the trial. The DSMB will review the informed consent and make recommendations on any changes to protocol. During the 18-month trial period, the DSMB will meet each quarter to review these data.

Harms: We used the SPRINT trial[4] adverse events (hypotension, dizziness, ED visits, acute kidney injury) for our study adverse events and provide an alert for when these are detected in the EHR to the study team, the patient, and the care team. Risks to participants include: 1) known adverse events from increased treatment and lowered BP, 2) psychological harm, and 3) loss of confidentiality. The adverse events are those common with medical and non-medical treatment of high BP and will be monitored by their primary care clinician.

Auditing: This study uses a single IRB through the University of Missouri-Columbia, #2091483.

Discussion

The Collaboration Oriented Approach to Controlling High BP (COACH) trial intends to understand how BP control can be improved by increasing adherence to patient-facing guideline-based recommendations. The focus of the trial is on home BP monitoring, as the starting recommendation underscores the key aspect of home-based efforts to assess and self-manage BP. The intervention also "closes the loop" between patient home monitoring, getting patient data to the care team in a way that provides actionable information for hypertension management designed to fit care team preferred workflows and management goals. The intervention, an enhanced version of COACH that includes BP data visualization, affectively enhanced visual summaries, and reminders about BP management, is based on core principles of Social Cognitive Theory, including self-efficacy, social support, outcome expectations, and self-regulation[32, 45-49]. The underlying premise is that higher affective alerting will increase accuracy in judgments about hypertension control and risk perception and motivate patients out of goal range to appropriate action, without creating excess anxiety, which will allow safe, efficient and effective behavioral and medication changes[32, 50-52].

There have been several other trials that address home BP monitoring. Bosworth et al.[53, 54] showed nurse-based telephone support coupled with home BP monitoring was more effective for BP control than usual care or telephone support alone. This effect was strongest for non-white patients. However, individual team-based coaching support is expensive and challenging to scale. Mobile health applications have shown promise in providing this support for key populations, including those with high BP, showing a -4.1 mmHg drop in SBP in a systematic review[20]. These trials generally depend on revised systems of care to enhance patient engagement, with the digital tool a part of the overall intervention COACH is designed to be a scalable electronic patient- and care team-facing intervention that does not require additional personnel to implement.

This trial intends to test whether a more advanced, tailored digital intervention can overcome these barriers in a pragmatic way – in essence, with minimal care redesign. To accomplish this goal, we leverage **Social Cognitive Theory (SCT)** to drive improved patient engagement to measure BPs and accomplish goals for BP lowering. We incorporate these principles along with tailored messaging informed by decision psychology into the intervention to drive engagement and uptake.

We also adapted the trial design based on substantial pre-implementation evaluation. To increase the likelihood of generalizable evidence from the trial, we performed a multimodal qualitative study. Results from the analysis were used to: 1) offer ad hoc and population-based referral techniques that matched high BP quality improvement initiatives in the practices; 2) change the intervention itself to ensure care teams were getting the information they needed; 3) identify additional personnel that participate in BP management, including pharmacists, panel coordinators, and medical assistants; and 4) ensure we had good bi-directional communication with the practices. Our implementation blueprint incorporates these elements and will be useful for researchers looking to implement studies that interdigitate with clinic workflow and minimize burden while maximizing benefit.

This trial is timely. Information exchange standards and regulations are advancing our ability to create highly functional digital interventions that can integrate directly into care. The 21st Century Cures Act and related regulations require healthcare organizations to release information to patients using relevant standards without extra effort. The COACH tool uses these standards (FHIR) to build a comprehensive and tailored tool that can incorporate specific patient context, overcoming previous gaps and enabling easier guidance. Our previous work showed that the available data through the EHR FHIR server was not sufficient to use standard guideline recommendations without adaptations needed to consider missing and inaccurate data;[24] these adaptations may help expand available data since we are exchanging data back to the EHR.

The results of this trial will help to understand how engagement with digital interventions can be enhanced with affective alerts and other design changes; and whether these changes can help lower blood pressure in a pragmatic way through home monitoring. The flexibility of the tool, its adherence to standards, and incorporation into a carefully designed implementation blueprint to fit into workflow will be helpful to future researchers and innovators. In addition, the explicit goal of placing minimal burden on care teams and engaging patients in achieving safe and effective BP control is likely to generate knowledge useful about how to optimally redesign primary care processes.

Ethics and Dissemination

Research ethics approval: Single IRB oversight through the University of Missouri-Columbia IRB, #2091483.

Protocol amendments: Key Study Personnel (KSP) plan to communicate important protocol modifications (e.g, changes to eligibility criteria, outcomes, analyses) to the appropriate parties (e.g, IRB, trial participants, DSMB).

Competing Interests: No, there are no competing interests for any author.

Consent and assent: KSP will obtain informed consent from potential trial participants through an electronic tool called REDCap.

Confidentiality: The Principal Investigators (PI) will be responsible for ensuring participants' privacy, confidentiality and data security. Data collection via REDCap will enhance data security. All data will be stored on secure encrypted, HIPAA compliant, SharePoint/OneDrive securely. COACH access has been strategically nested within the 3 sites' EHRs/patient portals to eliminate additional sign-ons and exposure to data threats. The

Data and Safety Monitoring Board (DSMB) will review any instances of loss of confidentiality and will review adverse events that meet the reporting requirements. The DSMB will make recommendations to AHRQ and the PIs concerning the continuation, modification, or conclusion of the trial.

Data Sharing Statement: Not Applicable

Ancillary and post-trial care: Care will always be directed by the care team, and the use of the tool or similar functions will be available after the trial is over.

Funding: The Agency for Healthcare Research and Quality (AHRQ) - R18HS028579

Dissemination policy: Trial results and the implementation details, including the logic and concepts from COACH, will be made available via publications, on Clinicaltrials.gov, and via open source mechanisms[27, 55].

Contributorship statement: DD, RK, AR, SC, VS, and WM collectively planned the study, collaborated on grant writing, and jointly drafted and reviewed this manuscript. VS conducted Qualtrics studies to gather feedback on the study components. EM and PG, acting as study coordinators at the Missouri site, facilitated study submissions, leveraging Missouri's role as the single IRB. They played integral roles in manuscript drafting and review. AG, the study coordinator at the Oregon site, contributed to the creation of site-specific documents and educational materials within the COACH application, in addition to drafting and reviewing the manuscript. LM established the REDCap survey database, significantly contributed to manuscript editing, and serves as the program manager for the study. BJ and ML, serving as patient co-investigators, provided valuable feedback on recruitment materials, the COACH interface, and overall study design. Authors affiliated with the COACH Consortium meet the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE). EC provided project administration. AY contributed to software development, validation, and visualization. MB engaged in data curation, software development, supervision, validation, and visualization for the COACH application. DC supported the conceptualization of the study, contributed to visualization, writing, and manuscript review, and serves as a member of the COACH advisory board. JS assisted with project administration at one of the clinics and provided resources essential for successful implementation. GF contributed to COACH methodology, software development, manuscript writing and review, and also serves on the COACH Advisory Board. KP aided in project administration at one of the clinics and participated in manuscript review. JP contributed to methodology, manuscript writing, and review. MS served as an engineer on the COACH team, assisting with software development. SM served as the statistician, contributing to formal analysis, visualization, initial manuscript drafting, and review.

Appendices

Appendix 1. CFIR Semi-Structured Interview Guide
Appendix 2. Patient Focus Group Guide
Appendix 3. Informed consent materials

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Table 1. RE-AIM measures and outcomes

RE-AIM Evaluation Measures		
Component	**Outcome Measures**	**Source**
Reach		
1. Number of eligible enrolled patients	CONSORT	REDCap - baseline survey
2. Differences from the eligible population	CONSORT	REDCap - baseline survey
Effectiveness		
1. Intervention effects on outcome	Primary	Electronic Health Record, patient portal
	Secondary	Electronic Health Record, patient portal
2. Increase in patient:	Social Cognitive Theory	Patient 2/6 month follow up survey
Adoption		
1. Number of Home BP recordings entered	Counts	Electronic Health Record, patient portal
2. Number of encountered study blocks	App usage	Electronic Health Record, patient portal
Implementation		
1. Number of portal/phone messages about BP during 6-month intervention period		Electronic Health Record, patient portal
2. Barriers to Implementation	Interviews	CFIR Evaluation
3. Increased/decreased burden of intervention	Interviews	CFIR Evaluation
4. physician/nurse/patient suggestions	Interviews	CFIR Evaluation
5. participant support needs	Email, phone outreach to study staff	REDCap ongoing events
Maintenance		
1. Number of patients who continue to use the app and BP cuff		Study Participant Tracking
2. Institutional use of tools beyond trial		CFIR Evaluation

Table 2. COACH Study Visit Schedule

Procedure	Baseline	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8	Week 24
Information Sheet, Consent, Screening, randomization	X							
Receive COACH related Instructions/materials	X							
Monitoring Block (2-4 Weeks)			If Needed post 2 weeks					
Goal Setting Block (1-2 Weeks)			If Monitoring block ends in 2 weeks		If monitoring block ends in more than 2 weeks			
Health Belief Survey	X							
Digital and Health Literacy	X							
UTAUT							X	X
REDCap Alerts								
REDCap Alerts (Control)								
AE Form*							X	X

*AE form continuously available

Figure Captions:

Figure 1: PRagmatic Explanatory Continuum Indicator Summary Tool-2 (PRECIS) Diagram

Figure 2a: COACH home page for enhanced arm; 2b: COACH home page for control arm

Figure 3: High BP warning (similar for low BP) for both groups

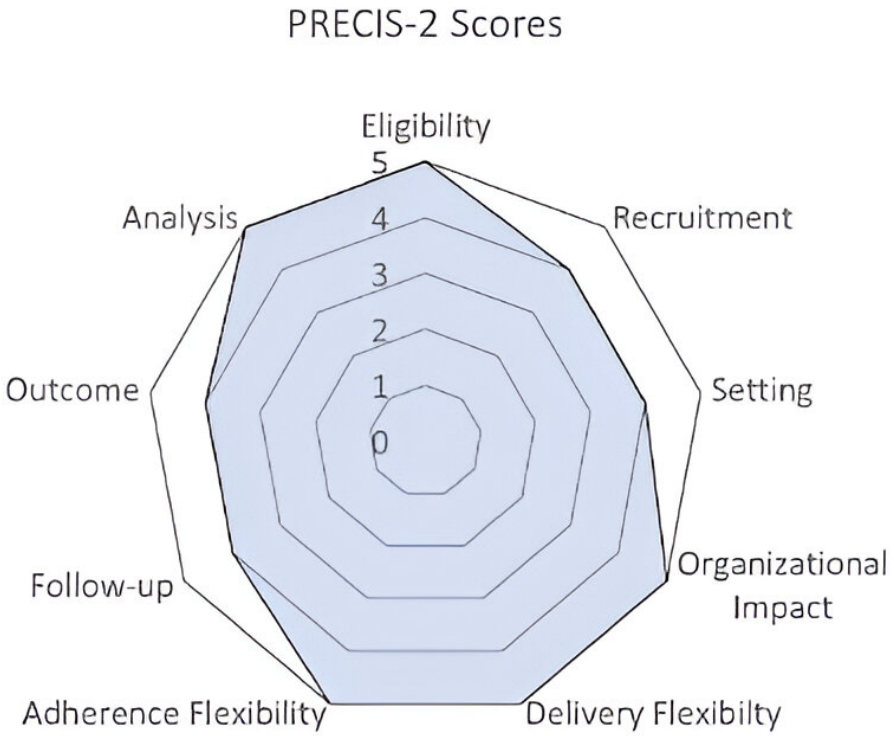

Figure 1: PRagmatic Explanatory Continuum Indicator Summary Tool-2 (PRECIS) Diagram

298x251mm (72 x 72 DPI)

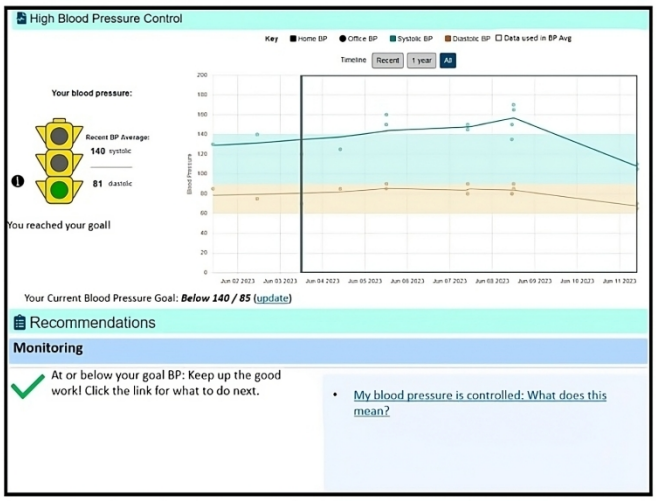

Figure 2a: Home page for enhanced arm COACH

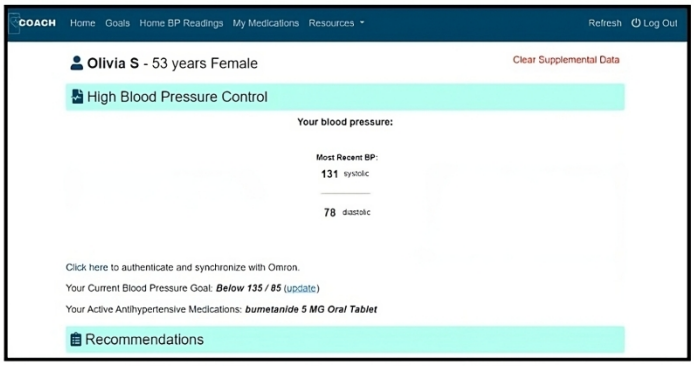

Figure 2b: Home page for control arm COACH

Figure 2a: COACH home page for enhanced arm; 2b: COACH home page for control arm

762x762mm (72 x 72 DPI)

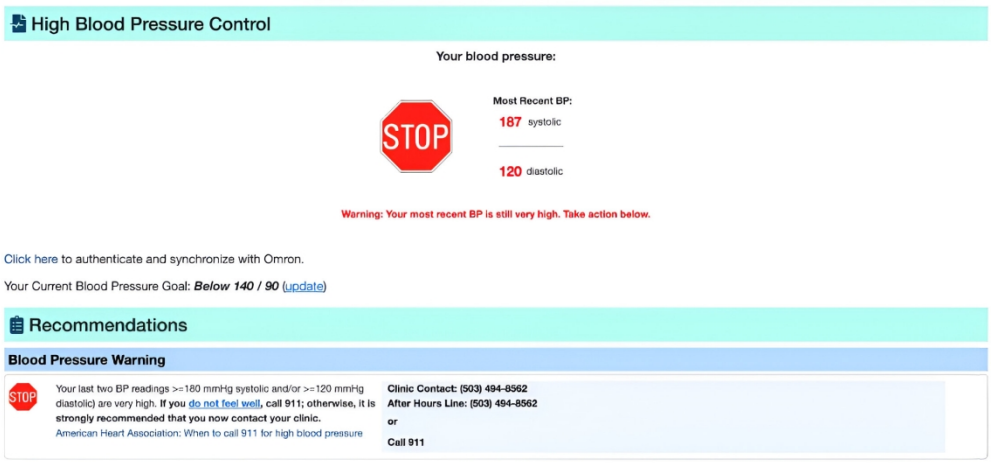

Figure 3: High BP warning (similar for low BP) for both groups

776x363mm (72 x 72 DPI)

Implementation of COACH: Semi-Structured Interview Guide

Notes to interviewer:

1. All questions will not be relevant for all stakeholders and will vary depending on the stage of implementation. Tailor questions by deleting questions that do not apply to stakeholder/stage – it is likely that more than half will be deleted for an appropriate interview of reasonable length)
2. The intervention = the COACH decision support tool to support patients in self-managing blood pressure, home blood pressure, and cardiovascular disease risk

Evidence Strength & Quality

1. What kind of supporting evidence or proof is needed about the effectiveness of the intervention to get staff on board?
    - Co-workers? Administrative leaders?

Relative Advantage

1. Is there another intervention that people would rather implement?
    - Can you describe that intervention?
    - Why would people prefer the alternative?

Adaptability

1. What kinds of changes or alterations do you think you will need to make to the intervention so it will work effectively in your setting?
    - Do you think you will be able to make these changes? Why or why not?
2. Who will decide (or what is the process for deciding) whether changes are needed to the intervention so that it works well in your setting?
    - How will you know if it is appropriate to make any changes?
3. Are there components that should not be altered?
    - Which ones should not be altered?

Trialability

1. Will the intervention be piloted prior to full-scale implementation?
    - [If Yes] Can you describe what your plans are for piloting the intervention?
    - [If Yes] What will the pilot look like?
2. Do you think it would be possible to pilot the intervention before making it available to everyone?
    - Why or why not?

- Would this be helpful?

Complexity

1. How complicated is the intervention?
    - Please consider the following aspects of the intervention: duration, scope, intricacy and number of steps involved and whether the intervention reflects a clear departure from previous practices.

Design Quality & Packaging

1. What is your perception of the quality of the supporting materials, packaging, and bundling of the intervention for implementation?
    - Why?
2. What supports, such as online resources, marketing materials, or a toolkit, are available to help you implement and use the intervention?
    - How do you access these materials?
3. How will available materials affect implementation in your setting?

Cost

1. What costs will be incurred to implement the intervention?

Patient Needs & Resources

1. To what extent were the needs and preferences of the individuals served by your organization considered when deciding to implement the intervention?
    - Can you describe specific examples?
    - Will the intervention be altered to meet their needs and preferences?
2. How well do you think the intervention will meet the needs of the individuals served by your organization?
    - In what ways will the intervention meet their needs? E.g. improved access to services? Reduced wait times? Help with self-management? Reduced travel time and expense?
3. How do you think the individuals served by your organization will respond to the intervention?

4. What barriers will the individuals served by your organization face to participating in the intervention?
5. Have you heard stories about the experiences of participants with the intervention?
    - Can you describe a specific story?

Peer Pressure

1. Can you tell me what you know about any other organizations that have implemented the intervention or other similar programs?
    - How has this information influenced the decision to implement the intervention?
2. To what extent are other units within your organization implementing the intervention?
    - How does that affect support for implementing the intervention in your own setting?
3. To what extent would implementing the intervention provide an advantage for your organization compared to other organizations in your area?
    - Is there a competitive advantage?
    - Is there something about the intervention that would bring more individuals into your organization, instead of another one in your area?

External Policies & Incentives

1. What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced the decision to implement the intervention?
    - How will the intervention affect your organization's ability to meet these measures, policies, regulations, or guidelines?
2. What kind of financial or other incentives influenced the decision to implement the intervention?
    - How will the intervention affect your organization's ability to receive these incentives?
    - How will the new intervention affect payment or revenue for your organization?

Structural Characteristics

1. How will the infrastructure of your organization (social architecture, age, maturity, size, or physical layout) affect the implementation of the intervention?
    - How will the infrastructure facilitate/hinder implementation of the intervention?
    - How will you work around structural challenges?
2. What kinds of infrastructure changes will be needed to accommodate the intervention?

- Changes in scope of practice? Changes in formal policies? Changes in information systems or electronic records systems? Other?
- What kind of approvals will be needed? Who will need to be involved?
- Can you describe the process that will be needed to make these changes?

Networks & Communications

1. Can you describe your working relationship with influential stakeholders?
2. Are meetings, such as staff meetings, held regularly?
   - Do you typically attend?
   - Who typically attends?
   - What proportion of staff typically attend?
   - How often are the meetings held?
   - What is a typical agenda? How helpful are these meetings?
3. How do you typically find out about new information, such as new initiatives, accomplishments, issues, new staff, staff departures?
4. When you need to get something done or to solve a problem, who are your "go-to" people?
   - Can you describe a recent example?

Culture

1. How would you describe the culture of your organization? Of your own setting or unit?
   - Do you feel like the culture of your own unit is different from the overall organization? In what ways?
2. How do you think your organization's culture (general beliefs, values, assumptions that people embrace) will affect the implementation of the intervention?
   - Can you describe an example that highlights this?
3. To what extent are new ideas embraced and used to make improvements in your organization?
   - Can you describe a recent example?
4. *This question can be open-ended or elicit percentages so that they add up to 100%. e.g., my culture is 50% Team, 40% entrepreneurial, 10% hierarchical.*

   Some people characterize culture in terms of four general types. To what extent would you characterize your culture as:

- Team (Clan) Culture (Flexible, Internal Focus): A friendly workplace where leaders act like mentors, facilitators, and team-builders. There is value placed on long-term development and doing things together.
- Hierarchical (Hierarchy) Culture (Control, Internal Focus): A structured and formalized workplace where leaders act like coordinators, monitors, and organizers. There is value placed on incremental change and doing things right.
- Entrepreneurial (Adhocracy) Culture (Flexible, External Focus): A dynamic workplace with leaders that stimulate intervention. There is value placed on breakthroughs and doing things first.
- Rational (Market) Culture (Control, External Focus): A competitive workplace with leaders like hard drivers, producers, or competitors. There is value placed on short-term performance and doing things fast.

Implementation Climate

1. *This question is likely to uncover topics to explore more within other sub-constructs, but be attentive to other themes that may not be included in your assessment.*

   What is the general level of receptivity in your organization to implementing the intervention?

   - Why?

Tension for Change

1. Is there a strong need for this intervention?
   - Why or why not?
   - Do others see a need for the intervention?
2. How essential is this intervention to meet the needs of the individuals served by your organization or other organizational goals and objectives?
3. How do people feel about current programs/practices/process that are available related to the intervention?
   - To what extent do current programs fail to meet existing needs? Will the intervention meet these needs?
   - How will the intervention fill current gaps?

Compatibility

1. How well does the intervention fit with your values and norms and the values and norms within the organization?
    - Values relating to interacting with individuals served by your organization, e.g. shared-decision making vs. being more directive?
    - Values related to referring to outside vendor-based programs vs. providing services by in-house staff?
2. How well does the intervention fit with existing work processes and practices in your setting?
    - What are likely issues or complications that may arise?

Relative Priority

1. Describe activities or initiatives that (appear to) have highest priority for you (for the organization)?
    - What kind of pressure are you feeling to accomplish this? Where is it coming from? Why?
2. To what extent might the implementation take a backseat to other high-priority initiatives going on now?
    - How important do you think it is to implement the intervention compared to the other priorities?
    - How important is it to others, such as your coworkers or leaders, to implement the intervention compared to the other priorities?
3. How will you juggle competing priorities in your own work? How will your colleagues juggle these priorities?
    - What are the other priorities?
    - How does the priority of implementing the intervention compare to other priorities in your organization? For your own work?

Organizational Incentives & Rewards

1. What kinds of incentives are there to help ensure that the implementation of the intervention is successful?
    - What is your motivation for wanting to help ensure the implementation is successful?
2. Are there any special recognitions or rewards planned that are related to implementing the intervention?
    - Can you describe them?
    - Will these be targeted to groups/teams/units or individuals?

Goals & Feedback

1. To what extent are organizational goals monitored for progress?
    - Can you give an example of monitoring in terms of the type of information, who is informed, and how?
2. Do you get any feedback reports about your work?
    - What do they look like? Content, mode, form?
    - How helpful are those reports?
    - How can they be improved?
    - How often do you get them? Where do they come from?
    - Who designed them?
3. *This question can be framed in terms of the intervention. For example, in a healthcare setting: How does implementation of the intervention align with organizational goals related to preventing*

    How does implementation of the intervention align with other organizational goals?

Learning Climate

1. Can you describe a recent quality improvement initiative or an implementation of a new program?
    - Can you describe the new initiative/program and the motivation to improve/implement it?
    - Can you tell me the major milestones or key accomplishments along the way?
    - What factors helped make it successful/fail?
    - Who were the key "players"?
    - What was your involvement?
    - Were people happy with the outcome/initiative?
    - Can you tell me about how leaders were involved? Who? Their roles? How they helped/hindered?
2. If you saw a problem in your own setting, what would you do?
    - Can you tell a story about a recent problem you resolved or initiative you participated in?
3. To what extent do you feel like you can try new things to improve your work processes?
    - Do you feel like you have the time and energy to think about ways to improve things?
    - Did you feel valued/respected by your supervisor for the role you played?
    - What role did your supervisor (or other leaders) play? What actions did they take?

Readiness for Implementation

Leadership Engagement

1. What level of involvement has leadership at your organization had so far with the intervention?
    - Do they know about the intention to implement the intervention?
    - Who are these leaders? How do attitudes of different leaders vary?
    - What kind of support have they given you? Can you provide specific examples?
2. What kind of support or actions can you expect from leaders in your organization to help make implementation successful?
    - Who are these leaders? How do attitudes of different leaders vary?
    - Do they know about the intention to implement the intervention?
    - What kind of support can you expect going forward? Can you provide specific examples?
    - What types of barriers might they create?

Available Resources

1. Do you expect to have sufficient resources to implement and administer the intervention?
    - [If Yes] What resources are you counting on? Are there any other resources that you received, or would have liked to receive?
    - What resources will be easy to procure?
    - [If no] What resources will not be available?
2. How do you expect to procure necessary resources?
    - Who will be involved in helping you get what is needed?
    - What challenges do you expect to encounter?

Access to Knowledge & Information

1. What kinds of information and materials about the intervention have already been made available to you?
    - Copies of materials?
    - Personal contact?
    - Internal information sharing; e.g., staff meetings?
    - Has it been timely? Relevant? Sufficient?
2. *This question may also be relevant to Engaging: Key Stakeholders.*

What kinds of information and materials about the intervention are planned for individuals in your setting?

- Copies of materials?
- Personal contact?
- Internal information sharing; e.g., staff meetings?
- Will it be timely? Relevant? Sufficient?

Knowledge & Beliefs about the Intervention

1. What do you know about the intervention or its implementation?
2. Do you think the intervention will be effective in your setting?
   - Why or why not?
3. How do you feel about the intervention being used in your setting?
   - How do you feel about the plan to implement the intervention in your setting?
   - Do you have any feelings of anticipation? Stress? Enthusiasm? Why?

Self-efficacy

1. How confident are you that you will be able to use the intervention?
   - What gives you that level of confidence (or lack of confidence)?
2. How confident do you think your colleagues feel about using the intervention?
   - What gives them that level of confidence (or lack of confidence)?

Individual Stage of Change

1. *Explore which level the individual is at using Rogers' (or Porchaska's Stages of Change) as a guide:*

   How prepared are you to use the intervention?

   - Knowledge stage (Precontemplation) - knowledge of key aspects of the intervention
   - Persuasion stage (Contemplation) - likes the intervention, discusses it with others, buys into it, has a positive view
   - Decision stage (Preparation) - intends to seek additional information and try it
   - Implementation stage (Action) - acquires additional information, uses intervention regularly, and has continued use

- Confirmation stage (Maintenance) - recognizes benefits, has integrated the intervention into routines, promotes use to others

Individual Identification with Organization

- *Responses to other questions may be (double) coded here. For example, buy-in to organizational or intervention-related goals may be elicited under Goals & Feedback, but may also be relevant here.*

Other Personal Attributes

- *The type of statements coded here will depend on study objectives, for example, locus of control, and other concepts from health or organizational psychology found to be related to a particular implementation.*

Planning

1. Can you describe the plan for implementing the intervention?
    - How detailed is the plan? Who knows about it? Is the plan overly complex? Understandable? Realistic and feasible?
    - What is your role in the planning process?
    - Who is involved in the planning process? What are their roles?
    - Are the appropriate people involved in the planning process? How engaged are they?
    - Do you plan to track the progress of implementation based on your plan?
    - What if you have to modify or revise your plan due to barrier, errors, or mistakes?

Engaging

Opinion Leaders

1. Who are the key influential individuals to get on board with this implementation?
2. What are influential individuals saying about the intervention?
    - Who are these influential individuals?
    - To what extent will they influence others' use of the intervention? The success of the implementation?

Champions

1. Other than the formal implementation leader, are there people in your organization who are likely to champion (go above and beyond what might be expected) the intervention?
    - Were they formally appointed in this position, or was it an informal role?
    - What position do these champions have in your organization?
    - How do you think they will help with implementation? Getting people to use the intervention?
2. What kinds of behaviors or actions do you think this individual/champion will exhibit?
    - For example, helping get senior leaders on board, helping solve problems? Or a small role?

Key Stakeholders

1. What is your communication or education strategy (not including training, see Access to Knowledge and Information) for getting the word out about the intervention?
    - What materials/modes/venues do you plan to use? For example e-bulletin boards, emails, brochures?
    - What process do you plan to use to communicate? For example, going to staff meetings, talking to people informally?
2. Who are the key individuals to get on board with the intervention?
    - To encourage individuals to use the intervention? To help with implementation?

Intervention Participants

1. How will you or your colleagues communicate to the individuals that are served by your organization about the intervention?
    - How will they participate in the intervention?
    - How will they access the intervention?

Executing

1. Has the intervention been implemented according to the implementation plan?
    - [If Yes] Can you describe this?
    - [If No] Why not?

Reflecting & Evaluating

1. What kind of information do you plan to collect as you implement the intervention?
    - Which measures will you track? How will you track them?
    - How will this information be used?

2. Will you receive feedback reports about the implementation or the intervention itself?
    - What will they look like? Content, mode, form?
    - How helpful do you think they will be?
    - How could they be improved?
    - How often will you get them? Where will they come from?
    - Who is designing them?
3. How will you assess progress towards implementation or intervention goals?
    - How will results of the evaluation be distributed to stakeholders?
4. Will feedback be elicited from staff? From the individuals served by your organization?
    - [If yes] What kind of feedback?
5. To what extent has your organization/unit set goals for implementing the intervention?
    - How will goals be communicated in the organization? To whom will they be communicated?
    - What are the goals? How and to whom will they be communicated?

Focus group 1 - guide for patients with hypertension and high blood pressure

[Introduction- to be read at the beginning of each focus group]
Thank you again for agreeing to participate in our study. What we plan to do today is to ask you some questions about COACH and how we can engage you and other patients with high blood pressure or hypertension, and if COACH can meet the informational needs of self-monitoring and self-management of high blood pressure. But before we get started, I'd like to go over a few "ground" rules:

- We would like to hear from each of you. So, we hope all of you will join in the discussion and share your thoughts. We know that some people find it easier to talk in a group than others. So, please be mindful and "share the air."
- These sessions will be recorded, and later the recordings will be transcribed. We will not identify you on our transcripts. Your name and contact information will be kept in a separate database. We discussed this as part of our consent process, but before we move forward, we would like to ensure everyone is comfortable with this.
- Because we are recording, we ask that everyone take turns speaking. Otherwise, it will be very difficult to hear what you are saying making it difficult to transcribe later on. Also, please make sure to speak up, so that we can hear you on the recording.
- There are no right or wrong answers. So, please feel free to disagree or share a different perspective. We know you will all keep a respectful tone.
- We are asking everyone to be candid about their thoughts. However, we also request that you keep what is said here confidential in order to respect everyone's privacy (including your own).
- Before we get started, does anyone have any questions?

Focus Group 1

Presenting the prototype screens (comments/questions for each of the screens, video, or overall) of application COACH (if there is one already)

- What is your experience with telemonitoring (MyChart/Health Connect) of your blood pressure, or other medical conditions?
    - Pros? Cons? Challenges?
- How does your doctor usually communicate with you about your most recent BP measurement?
    - In what type of clinical situations is communication more likely? (e.g., medication or dose change, symptoms of low BP, side effects, etc.)
    - During a visit vs. between visits?
- How does home monitoring of your blood pressure make you feel, regarding managing your hypertension ?
- Do you know when and how to contact your healthcare team to seek help regarding your BP?
    - Could something like COACH help you with this? If so, how?
- What concerns do you have about managing your own BP at home?
    - Is there anything that would keep you from doing this?

    - What helps you (or would help you) do this?
    - Why/when might you not do this?
- What do you think you would need in terms of support/resources (like gamification) for you to continue to measure your BP at home? For example, education, encouraging texts/portal messages, etc.?
- What is your understanding of the "COACH" EHR visualization tool?
    - What are your initial thoughts on the "COACH" EHR visualization tool?
    - Would you use a tool like this? Why or why not?
    - In what situations do you think COACH would be most helpful? (e.g., medication change, managing/tracking improvements in habits and lifestyle?
- How would you prefer to receive feedback about entered home BP values/COACH activities?
    - What format of obtaining feedback on entered home BP values would you prefer? For example, telemonitoring, paper, or text? Why?
    - From whom would you find it valuable to receive feedback? Doctor, nurse, other member of care team, algorithmic or AI?
- Do you like the idea of setting your own goals in COACH? What do you think about customization of goals as per individual patient being integrated into COACH?
- Describe how you would prefer your medication history be presented in COACH?
- How often/when do you think you would you likely use COACH to self-monitor and self-manage your blood pressure in home?
- Do you think notifications/alerts would be useful tools to remind you to monitor your BP? Is so, what sorts of alerts would you prefer to receive (text messages, pop-up messages, etc., and how often would you want them? Describe what you feel you would need in terms of notifications/alerts in COACH, and how do you feel these notifications/alerts might be useful in terms of reminding you to monitor your BP?
- How can we make this experience better for you using COACH to self-monitor your BP? Do you have enough information/guidance to do so, etc.?

IRB # STUDY00024520

CLINICAL RESEARCH CONSENT AND AUTHORIZATION
SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Collaboration Oriented Approach to Controlling High Blood Pressure (COACH)

PRINCIPAL INVESTIGATORS: Richelle Koopman, MD, MS (573) 882-0598
David Dorr, MD, MS (503) 418-2387

CO-INVESTIGATOR: William Martinez, MD, MSc (615) 322-3000

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not. This is a multi-site study with University of Missouri-Columbia (MU), Oregon Health & Sciences University (OHSU) and Vanderbilt University Medical Center (VUMC).

PURPOSE: The purpose of the study is to learn how well the COACH application can help lower blood pressure. We are hoping to find out ways to help people manage high blood pressure.

DURATION: Your participation in the study will consist of three surveys over 6 months and blood pressure monitoring from home. Surveys will last up to 20 minutes each.

PROCEDURES: If you decide to participate, you will be asked to complete surveys now, in 8 weeks and in 6 months. You will also be asked to use the COACH application and to monitor your blood pressure during those 6 months.

RISKS: The main risk is a loss of confidentiality. You may also feel side effects that are common during blood pressure management.

BENEFITS: You may not directly benefit from taking part in this research. The COACH application may help you reduce your blood pressure.

ALTERNATIVES: You may choose not to participate in this study, may receive standard blood pressure treatment or participate in another study if one is available.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Study Team if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

IRB # STUDY00024520

Research Consent and Authorization Form

PROJECT TITLE: Collaboration Oriented Approach to Controlling High Blood Pressure (COACH)

PRINCIPAL INVESTIGATORS: Richelle Koopman, MD, MS (573) 882-0598
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This is a multi-site study with University of Missouri- Columbia (MU), Oregon Health & Sciences University (OHSU) and Vanderbilt University Medical Center (VUMC).

CONTACT INFORMATION:

Email: COACH-OHSU@ohsu.edu
Phone: 833-462-9191

WHO IS PAYING FOR THE STUDY? *Agency for Healthcare Research and Quality (AHRQ)*

WHO IS PROVIDING SUPPORT FOR THE STUDY? *None*

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY? *No*

WHY IS THIS STUDY BEING DONE?

You have been invited to be in this research study because you have high blood pressure and your clinician or care team recommend that you participate in a home blood pressure monitoring program. The purpose of this study is to evaluate the effectiveness of the COACH application to lower blood pressure using evidence-based research and patient participation to maximize effectiveness.

A total of 550 patients will be enrolled into the study. Patients are asked to participate in this study for 6 months. You will be asked to monitor your blood pressure using the COACH application and complete surveys.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

In addition to your regular blood pressure management regiment, you will use the COACH web-based application to measure your blood pressure regularly. You will be provided a link that directs you to instructions on how to use the COACH application. You will be asked to measure your blood pressure regularly from your home. We will provide you with a blood pressure cuff with Bluetooth connection to use at home and record your results in COACH. You will receive information about your blood pressure readings and may receive additional recommendations. Your health record information including medications and blood pressure will be accessed by COACH.

You will complete surveys at three time points. The surveys will ask questions about how you manage your health and your experience using the COACH application.

Below is a breakdown of study procedures you may expect to complete as a participant in this study:

	Baseline Day 1	Week 8 (2 months)	Week 24 (6 months)
Consent Discussion, Screening questions and Survey #1	X		
Receive information on how to use COACH	X		
Survey #2		X	
Survey #3			X
Study payment for completing survey #3			X
Total time	30-60 minutes	20-25 minutes	20-25 minutes

WILL I RECEIVE RESULTS FROM THE STUDY?
You will not receive results from this study. However, your care team will be notified when your blood pressure is high (>180mmHg/120mmHg) or low (<90mmHg/60mmHg).

If you are interested in staying informed about the progress being made on the development of the application, and continuing to contribute to the development process, we may ask for your permission to contact you again in the future.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?
Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. You may also experience some side effects commonly experienced when people manage their blood pressure could include dizziness.

PERMISSION TO USE YOUR PROTECTED HEALTH INFORMATION:
State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.

You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

In this study we will take steps to keep your personal information confidential, but we cannot guarantee total privacy. We will be deidentifying information for data analysis.

Some identifiers about you will be obtained from your health records and are necessary for this research. The identifiers will include your name, address, dates related to you, phone numbers, email addresses, medical record number, social security number.

We may have to release this information to others for example, if the study is audited. However, we would try to do so without information that could identify you. This release could be to the Institutional Review Board (ethics review committee) overseeing the study at the University of Missouri, the Agency for Healthcare Research and Quality, or Office of Human Research Protection (agencies that oversee research). Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.

We may continue to use and disclose your information as described above indefinitely to disseminate research findings and results.

Some of the information collected and created in this study may be placed in your medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your medical record. If you have questions about what study information you will be able to access, and when, ask the study team.

After you join the study, you can choose to receive all future survey links and reminders by text message. If you choose this option, you are giving us permission to share your phone number with our vendor Twilio Inc. to send you these text messages.

We will limit the content of the text messages to general information such as survey links and reminders to complete your survey. Even so, these messages may contain information that you wish to keep confidential. Text messaging is not encrypted, messages can be intercepted by others, viewed by people who see your phone or sent to the wrong person, and may not be confidential.

If, at any point, you no longer wish to receive text messages from the study team, tell us by sending an email to COACH-OHSU@ohsu.edu or calling this number 1-833-462-9191, and we will stop sending you text messages.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no cost to you or your insurance company to participate in this study. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your medical condition. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

If you remain in the study and complete the final survey at 24 weeks (6 months), you will receive a $20 payment via electronic gift card. The gift card will be delivered via email and you will have an option to choose between Amazon, Walmart or Target.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact **COACH-OHSU@ohsu.edu**.

If you are injured or harmed by the study procedures, you will be treated. Any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

WHERE CAN I GET MORE INFORMATION?

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Richelle Koopman at koopmanr@health.missouri.edu or other members of the study team at COACH-OHSU@ohsu.edu. or call 833-462-9191.

If you have questions about your rights as a research participant, please contact the MU Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?

As a participant in this study we will ask you to monitor you blood pressure regularly and record it in the COACH application. We will also ask you to complete surveys at three time points during the study.

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the study team if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

COACH Coordinator: COACH-OHSU@ohsu.edu (one email for all 3 sites)

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

The information that we will collect from you will not be stored with your name or any other identifier. Therefore, there will not be a way for us to identify and destroy your materials if you decide in the future that you do not wish to participate in this research.

You may be removed from the study if the investigator or funder stops the study, your primary care provider believes it is not safe for you to continue with the study, or if you meet the exclusion criteria after signing this consent document.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study. We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
	6b	Explanation for choice of comparators	n/a
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
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Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
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Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Study Protocol: Collaboration Oriented Approach to Controlling High blood pressure (COACH) in adults - A Randomized Controlled Trial

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Title: Study Protocol: Collaboration Oriented Approach to Controlling High blood pressure (COACH) in adults - A Randomized Controlled Trial

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Abstract

Introduction Hypertension, the clinical condition of persistent high blood pressure (BP), is preventable yet remains a significant contributor to poor cardiovascular outcomes. Digital self-management support tools can increase patient self-care behaviors to improve BP. We created a patient- and provider-facing clinical decision support (CDS) application, called the Collaboration Oriented Approach to Controlling High BP (COACH), to integrate home BP data, guideline recommendations, and patient-centered goals with primary care workflows. We leverage Social Cognitive Theory principles to support enhanced engagement, shared decision-making, and self-management support. This study aims to measure the effectiveness of the COACH intervention and evaluate its adoption as part of BP management.

Methods and analysis. The study design is a **multi-site,** two-arm hybrid Type III implementation randomized controlled trial set within primary care practices across three health systems. Randomized participants are adults with high BP for whom home BP monitoring is indicated. The intervention arm will receive COACH, a digital web-based intervention with **effectively enhanced** alerts and displays intended to drive engagement with BP lowering; the control arm will receive COACH without the alerts and a simple display. Outcome measures include BP lowering (primary) and self-efficacy (secondary). Implementation pre-planning and post-evaluation uses the Consolidated Framework for Implementation Research and RE-AIM metrics with iterative cycles for qualitative integration into the trial and its quantitative evaluation. The trial analysis includes logistic regression and constrained longitudinal data analysis.

Ethics and Dissemination. The trial is approved under a single IRB through the University of Missouri-Columbia, #2091483. Dissemination of the intervention specifications and results will be through open-source mechanisms.

Strengths and limitations of this study

Limitations

- The study's utilization of participants solely from three academic health centers in the United States might restrict the applicability of the results to wider demographics.

- The eligibility criteria's exclusion of non-English speakers and those not enrolled in patient health portals might introduce selection bias, potentially limiting the sample's representativeness.

Strengths

- The study employs a pragmatic trial design, which allows for the evaluation of interventions in real-world clinical settings, enhancing the generalizability of the findings to routine practice.
- Statisticians, investigators, and auditors collecting data are blinded to allocation status, reducing the risk of bias in outcome assessment.
- The study design, including recruitment strategies, aligns with clinic preferences and involves both routine office visits and population-based identification, providing flexibility and maximizing the potential participant pool.

Introduction

High blood pressure (BP) caused by essential hypertension is one of the most common conditions among adults in the United States (US)[1]. High BP alone rarely has significant symptoms, but sustained high BP, or hypertension, increases the risk of heart attack, stroke, heart and kidney failure[2]. The likelihood of adverse cardiovascular outcomes begins to rise at low BP of 115/75 mmHg, and for every twelve-point increase in average BP, the risk doubles [3]. In the US, rates of uncontrolled BP continue to increase, with 46% of adults having Stage 1 (130/80 – 139/89 mmHg) or worse hypertension[1]. Despite advancements in overall health outcomes, BP control has remained poor, with less than half of adults with hypertension meeting a goal of < 140/90 mmHg[1].

Recent studies indicate that effectively managing BP involves navigating a narrow therapeutic window. Overly aggressive treatment increases the risk of significant comorbidities like kidney damage, hypotension, and mood disorders[4]. Evidence suggests that engaging patients directly in intensive goal setting, shared care planning around nonpharmacologic and pharmacologic treatments, and self-monitoring for effectiveness and adverse events reduces the risk of cardiovascular events[5]. Appropriately lowering BP without minimizing adverse events is essential for optimizing cardiovascular health and improving patient outcomes. Protocols for BP have remained largely driven by manual decision-making and existing clinical workflows, improving processes but not outcomes. Digital interventions involving Clinical Decision Support (CDS) systems can broaden efforts, but the complexity of high BP has led to mixed successes[6-10]. Hicks et al.[9] showed no significant difference in high BP management using a CDS intervention with providers, while several other CDS trials using multidisciplinary, multifaceted interventions, often including patient engagement and support, have shown reductions in BP and improved control[6, 7, 10, 11].

An essential component of controlling high BP involves empowering patients to manage their condition themselves by regularly monitoring their BP at home and adjusting their approach based on frequent readings. Review of these home data by the patient's health care team is an evidence-based component of hypertension management, but has been historically difficult to integrate into the care team's workflow.[12, 13]

Personalization of BP care plans based on patient needs and experience is also required[12, 14-17]. Patients are encouraged to change health behaviors such as limiting salt intake[18], losing weight[16], stopping smoking[16], adhering to pharmacological treatment plans, and simultaneously self-monitoring for adverse effects. Engaging patients in a process to self-monitor and manage conditions has been extensively studied. Team-based interventions with consistent support for motivation, a focus on self-efficacy, and consideration of affective, or emotional language, may be the key to enhancing engagement.[19] However, uptake is limited, and these approaches are expensive[20]. Digital interventions may be able to provide similar effects, but so far have had less success[21]. This protocol describes a digital intervention study that combines motivational messages with education, counseling, and support to increase patient BP knowledge and self-management capacity[13, 22]. Given our enhanced capability to provide patient-facing CDS[23] and enhanced electronic care planning, integrating CDS thoughtfully into patients' self-management routines is expected to improve their self-efficacy and improve control of chronic illness. Integration requires addressing traditional barriers to CDS integration addressing 5 rights – right person, right format, right time, right channel, and right information – and avoiding reminder fatigue and enhancing motivation with digital interventions.[19]

This intervention is a patient-facing high BP CDS web-based digital tool known as the Collaboration Oriented Application for Controlling High BP (COACH). COACH uses the Fast Healthcare Interoperable Resource (FHIR) standard to incorporate eight extant national and international guidelines[23] into standardized, interoperable CDS and uses the AHRQ Patient-Centered Clinical Decision Support framework[24] to engage patients, caregivers, and care teams in a collaborative implementation process. The trial will implement COACH across multiple clinic sites spanning three major health systems and in the nation's two leading EHR vendor platforms: EPIC and Oracle. Our primary objective is to evaluate the effectiveness of the application at lowering BP via a randomized controlled trial (RCT) comparing two versions of COACH that provide reminders and displays with high affective content (enhanced COACH) versus low affective content (basic COACH) to test improved engagement and results. We will employ a mixed methods design, with qualitative

inquiry nested within the RCT, secondary RE-AIM, and social cognitive theory outcomes, and iterative qualitative evaluation of implementations across sites.

COACH was developed with a broad range of patient and clinician viewpoints by: 1) incorporating input from patients and providers throughout the entire lifecycle of CDS[25, 26]; 2) customizing the COACH CDS to align with patient and care team preferences, values, and objectives; and 3) disseminating the open source application and underlying logic. The application is intended to be scalable through standard implementation frameworks, CDS artifacts, and implementation guides[27] that can be adopted beyond this protocol. For interoperability, we use a standard-based, structured process that re-uses concept and value sets from standard terminologies whenever possible while using robust techniques to develop new sets and make them available for future innovators.

Trial Design: The COACH study is a patient randomized multi-site, single-blind, hybrid type III implementation design[28] pragmatic trial leveraging mixed methods[29] using implementation science and informed by Social Cognitive Theory to test the effectiveness of the enhanced COACH application versus basic COACH at lowering BP. The trial plans to enroll 550 participants who will be randomly assigned in a 1:1 ratio to the intervention or the control arm (275 per arm), stratifying by 3 enrollment sites. Outcomes will be collected from home BP measurements entered manually or via Bluetooth link into the COACH application by study participants and via electronic questionnaires completed by participants at baseline, 8 weeks (2 months) and 24 weeks (6 months).

Methods

Pragmatic Design: The pragmatic trial aspects include broad inclusion criteria, no scheduled research visits, tailored workflows within clinic care teams, no clinical staff responsibilities to deliver the intervention, and flexibility in delivery within each site. We employed the PRECIS-2 tool (Pragmatic Explanatory Continuum Indicator Summary) to compare the trial to routine care settings[30]. Figure 1 highlights scores from 9 PRECIS-2 domains, where 1 is explanatory, idealized clinical trial conditions and 5 is pragmatic, closely matching routine care conditions. **Eligibility (5) and Recruitment (4)** All patients with high BP seen in primary care in

the last year will be eligible; these thresholds are standard for determining ongoing home BP monitoring. **Setting (4)** Primary care practices at the participating sites. **Organizational impact (5)** The trial will require no additional staff or modifications to usual care. **Flexible delivery for the practice (5) and adherence for the patient (5)**. The delivery of the application aligns with standard practice for home BP monitoring. The intervention offers initial training for providers to orient them to referral and clinical workflows. **Follow-up (4)** There are no scheduled research visits. Most measurements (clinic encounters, BP data, events, messaging) will be gathered from the electronic health record (EHR). Some additional measures outside usual care (e.g., self-efficacy) will be collected on remotely administered surveys. **Measurement (4)**. Measurements will be part of routine care and the COACH application and will not require additional care team time or effort.

Pre-implementation implementation science evaluation: In preparation for the trial, we conducted a pre-evaluation to explore implementation readiness at each intervention site, including patient perspectives (See Appendix 1 and 2). We utilized a qualitative design and employed patient co-investigators, informed by the Consolidation Framework for Implementation Research (CFIR)[31] domains: Innovation, Outer Setting, Inner Setting, Individual, and Implementation process. Results from this evaluation included dozens of programming and implementation recommendations to improve COACH integration. The research and development teams made programming modifications to the COACH application and applied the implementation recommendations, where possible, to ensure the protocol was pragmatic. Implementation recommendations included referral, intervention design, safety monitoring, integration into care, and ongoing monitoring. Programming changes included more guidance for patients, simpler text, more streamlined workflow and higher contrast display screens.

Patient Involvement: Patient involvement was integral to the development of the COACH clinical trial, as our funded Patient Co-Investigators (Co-Is) actively contributed to incorporating patient preferences. Through focus groups in the pre-implementation phases, patient feedback refined the development process, enhancing the usability of the COACH app and facilitating smoother implementation. Co-Is also played a pivotal role in grant

writing, offering essential insights into app usability and priorities. Their involvement extended to building recruitment materials and enhancing the COACH app. Continuously engaged, they shape plans for disseminating study results to linked communities, ensuring a patient-centered and inclusive approach throughout the study process, from planning dissemination to sharing findings.

Study Setting: Participants are identified from primary care practices associated with three academic health centers (sites) in the United States. The three sites are Oregon Health & Science University (OHSU), University of Missouri-Columbia (MU) and Vanderbilt University Medical Center (VUMC). Participating primary care practices will include Family Medicine and Internal Medicine practices affiliated with each institution. Funding for the study spans from July 2022 to June 2025, with enrollment scheduled to begin in January 2024.

Eligibility Criteria: Eligible participants are adults aged 18-100 years who communicate in English, receive care at a participating primary care clinic, enrolled in the site's patient health portal and with a visit in the last year. The participant must have elevated BP, defined as a single BP of >140 (>135 home) systolic or >90 (>85 home) diastolic at the current visit or the average of the last 4 BPs is >140 systolic or >90 diastolic, and have a clinician recommendation for a home BP monitoring program. Participants are excluded if they are pregnant at the time of consent, have severe cognitive impairment in the opinion of the clinician, are on hospice care and/or have a life expectancy of less than 2 years, have end-stage renal disease, or for whom tight BP control presents a greater than average risk for falls, dizziness, electrolyte disturbances, hypotension, or active heart failure or patient has any other disease or disorder that in the opinion of the investigator or the patient's primary care clinician, could put participants at risk and affect trial results, or hinder participation will exclude them from participating. COACH includes participants with secondary hypertension as the main objective is to control hypertension, no matter what the cause.

Interventions: Intervention and control groups will have access to the COACH application: intervention will receive enhanced features (Figure 2a), including affective reminders and visualizations, while the control group will receive simpler displays (Figure 2b). All groups will receive safety-related reminders. Reminders include screening, monitoring, self-management goal setting, and prompts to discuss medications (intervention), and significantly high or low BP alerts and suspected adverse events (both groups; see Figure 3). Participants in both groups receive a validated dual-channel, Bluetooth-enabled, home BP monitor (Omron 7 Series® Wireless Upper Arm BP Monitor) with instructions for use.

Outcomes: The **primary** outcome measure is BP control, defined as office < 140/90 or home < 135/85 average of the last set of blood pressures (defined as 12 home or 4 office, whichever are most recent) at 6 months as recorded by participants via home BP measurement and/or at scheduled clinic encounters. Control levels for home and office come from the ACC/AHA guidelines.[5] **Secondary outcomes** include the average reduction in systolic and diastolic BP after 6 months from the initial BP measures at enrollment, evaluate demographic factors contributing to blood pressure control and changes in key Social Cognitive Theory measures using a health beliefs survey from baseline to 6 months[32, 33]. Technology acceptance and usability will be measured from the Unified Theory of Acceptance and Use of Technology (UTAUT) model[34]. The UTAUT model was developed as an extension of the Technology Acceptance Model and is routinely used in health science research to understand factors associated with successful adoption and sustained use of mHealth interventions. UTAUT domains include performance expectancy (i.e., the belief that using the system will be useful or create gains), effort expectancy (i.e., the perception that the system is easy to use), social influence (i.e., belief others think they should use the system), and facilitating conditions (i.e., belief there is sufficient organizational and technical support to use the system).

RE-AIM outcomes. As part of the implementation evaluation, we will assess the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) metrics and concepts shown in Table 1. Using the CFIR framework as

a guideline, the evaluation will take a mixed methods approach, with iterative cycles of qualitative and quantitative assessments to understand overall implementation successes and challenges. To measure Reach, the total primary care populations from each clinic will be compared to enrolled participants to understand differences in eligible and enrolled populations. Adoption will be measured via the COACH app for both patients and clinicians: log-ins, consistent BP tracking, and interaction with the recommendations. For Implementation, semi-structured interviews and a clinician survey will be used to understand the barriers and facilitators of using COACH in practice. Finally, Maintenance will assess the sustainability of the application through semi-structured interviews.

Participant Timeline: Procedures for the study are in Table 2. Consent is obtained through a REDCap e-consent module, and patient training is completed online with support by phone and email. Once enrolled and randomized, patients are placed in the monitoring block for 4 weeks or until they have 12 BPs. Reminders are provided through the monitoring block, with augmented reminders for the intervention arm. Once the monitoring block is over, patients are prompted to reflect on goals, including contacting their care team. This cycle repeats for up to 6 months. Patient surveys occur at baseline, week 8, and week 24; adverse event survey links are constantly available.

Sample Size and Power: The number of participants we plan to enroll and randomize is 550 across all three sites. We anticipate that 40% of participants will come from OHSU (n=225), 40% from MU (n=225), and 20% (n=100) from VUMC. Actual enrollment may differ, and enrollment will continue until 550 participants are randomized.

The total sample size was determined based on a test of two independent proportions (percent with controlled BP at the end of the trial) assuming a level of significance equal to 0.05 (two-sided) and power equal to 90%. We anticipate the intervention arm will increase from 0% controlled at baseline to 40% at 6 months while the control arm will increase from 0% to 25%. Under these assumptions, 406 evaluable participants are required,

meaning those with complete data at the 6-month time point. We increased the total enrollment projection to account for attrition and/or uncertainty in projected changes.

Recruitment: Recruitment will take place at primary care practices affiliated with the three sites via two methods: population-based identification using registries and visit-based identification. Consistent with our pragmatic approach, individual sites, and practices can prioritize the recruitment method that best suits their environment and resources. The target recruitment period is from January 2024 to June 2025.

Recruitment mechanisms:

1) Routine office visit (primary): Clinicians will identify a potential participant during a routine office visit where the patient's BP would prompt pharmacologic treatment according to the ACA/AHA guidelines. The clinician can recommend home BP monitoring and initiate a standard patient portal recruitment message with information and links to complete screening, consent, and enrollment.

2) Population-based recruitment: Clinicians or team members identify empaneled, active individuals with high BP through an EHR-based report. The responsible clinician or authorized care team member will send patient portal messages in bulk to a set of selected patients, informing them of the study and providing links to complete screening, consent, and enrollment. Population-based chronic condition identification and management are employed to varying degrees at each of our study sites.

Methods: Assignment of Interventions

Enrollment After receiving an invitation to participate, patients are directed to a REDCap survey for study information. The patient reviews an information sheet, then begin the eligibility screening process, as defined

above. Eligible participants must give informed consent (see Appendix 3) by signing an electronic form in REDCap, then proceed to the baseline survey.

Randomization Upon enrollment and after completing the baseline survey, participants are randomized with a stratification by site to the COACH enhanced intervention arm or COACH basic control arm by the central coordinating team at OHSU using the randomization tool in REDCap. The randomization scheme is stratified by study site and implemented using a blocking strategy to ensure equal numbers of participants assigned to intervention and control arms within each site.

Allocation- concealment mechanism: The automated randomization system in REDCap can obfuscate the allocation of all patients, and – other than stratification by site – does not depend on time or previous allocation.

Blinding (masking): Statisticians, investigators and auditors collecting BP data from the EHR will be blinded to allocation status. Study participants will be told that the study is testing a home BP monitoring program's effectiveness, but not that it is comparing two care models. Clinicians and care team members will see the enhanced (or intervention) version of COACH. Patients will not be blinded since the COACH display is different for each arm. Once the trial is over, analysts will be provided data with an obfuscated study arm.

Methods: Data Collection, management, and analysis

Data collection: We will use several techniques to gather data. First, COACH itself will gather data through FHIR connections to the EHR, pulling all relevant clinical information about the patient. COACH will track home BPs received through manual entry and electronic connections to the Omron mobile application. COACH will also store key information about use, including logins and interaction with recommendations. Second, all surveys will be captured through REDCap hosted at OHSU[33, 35]. REDCap is a secure, broadly used research

survey tool that has been integrated with COACH. Standard surveys include the Health Belief Survey; Digital[36] and Health Literacy[37]; and a modified UTAUT survey focused on COACH; schedule is provided in Table 2. Patient demographic collection and adverse events will be collected via REDCap. Finally, as part of implementation evaluation, we will gather qualitative data through clinic site visits, observation, focus groups, and interviews; these data will be recorded, and transcribed verbatim.

Data management: All tools used in the study have secure access to the underlying data with auditing capabilities for use; in this secure network, we will store all versions of the study data, and manage secure storage. In addition to extracting data directly from the EHR, patients will enter their self-reported data. For qualitative transcripts, the original recordings will be kept until study completion.

Qualitative data collection: During the implementation and trial, we will conduct bi-monthly video calls with implementation sites. Implementation site-identified stakeholders and champions will be the participants in the calls. We will use a template approach to guide the call to ensure coverage of relevant topics, altering the template for the stage of implementation and known/evolving context and concerns. We will encourage all participants to voice unique concerns, allowing us to monitor implementation progress, identify barriers, troubleshoot problems, and identify any new and unexpected uses of the tool, including both adverse and beneficial outcomes.

Statistical methods & 20b and c:

Quantitative analysis. The intervention effect on the primary outcome of BP control will be tested using a logistic regression model[38] with a binary variable for the intervention arm and health system as a categorical variable[39], adjusting for baseline BP, as defined above[40]. Rates of control in each arm and treatment differences will be calculated using mean predicted probabilities from the logistic model[41]. Because randomization is stratified by site, we will include this as a categorical variable for accurate variance estimates

and will also adjust for baseline BP. Estimates of the probability of control in each arm and treatment differences will be calculated using mean predicted probabilities from the logistic model.

The secondary outcomes of reduction in systolic and diastolic BP after 6 months will be evaluated with a model sometimes described as constrained longitudinal data analysis (cLDA), in which the two-time points are treated as panel data with an observation for each. The model will include a term for time (baseline/final) and an interaction term for the study arm, which constrains the arms to the same baseline mean as expected in a randomized trial but estimates different changes over time. A random effect for patients will be included for the correlation between baseline/final measurements. This model is statistically efficient and accommodates missing measurements, so it is a good fit for the intention-to-treat approach.

Continuous secondary outcomes, such as reduction in systolic and diastolic BP after 6 months, will be evaluated with a mixed-effects regression model[38] in which the baseline and 6-month time points are treated as panel data with an observation for each. This model includes a term for time (baseline/final) and an interaction term for the study arm. Baseline means are thus constrained to be equal as expected in a randomized trial but changes over time differ. A random effect for patients will model the correlation between baseline/final measurements. This model is statistically efficient and accommodates missing measurements. No adjustments for multiplicity are planned because outcomes are pre-specified and correlated.

Adherence: Participants will be included in the analysis once the application and/or home BP monitoring once randomized. Their use of the application will be encouraged by the intervention, but analysis will not depend on their use.

Qualitative analysis. After all site visits are complete, we will arrange transcription of audio using Rev.com. All recorded interviews will be transcribed, verbatim, and deidentified for qualitative analysis using the web-based analysis software Dedoose v9[42]. Investigators will create case memos with the CFIR construct ratings for each site across all three health systems and identify CFIR constructs most relevant to the planned

implementation across all sites. We will use the method described by Damschroeder and Lowery[43]: 1) assign each site transcript to a pair of analysts who will each independently code the transcripts using the CFIR framework as a coding template with a deductive qualitative analytical approach, 2) develop/build-on case memo for each site, 3) large group discussion with investigators, 4) refine case memo, 5) large group assigns construct ratings, 6) case memo with construct ratings. In step 5, the large group will come to a consensus on CFIR construct ratings and score each case/clinic on the identified constructs. It is conventional to rate each CFIR construct from -2 (strong negative influence on implementation) to +2 (strong positive influence implementation), including 0 (neutral influence on implementation). This process will result in a high-level summary matrix of clinic implementation sites rated on multiple CFIR domains representing positive and negative influences of implementation influences across the 3 health systems[44].

Data from bi-monthly implementation calls will be analyzed in the same manner and will be added to our existing pre-implementation CFIR case memos to provide a rich description of the course of the implementation in each context, allowing comparison across sites, giving insights into both common themes across sites and context-specific differences. This robust synthesis and comparison of experiences across sites and EHR platforms will provide valuable system-level information to inform new implementations, emphasizing common experiences and highlighting relevant context-specific facilitators and barriers. In addition to the traditional publication of findings, we will leverage the affiliations of our advisory group and the AHRQ CDS Connect Community as outlets for dissemination.

Data monitoring: The Principal Investigators (PI) will be responsible for ensuring participants' safety daily. In addition, the study has an empaneled a 12-member Advisory Board composed of national experts, including patient experts, to act as a Data and Safety Monitoring Board (DSMB) and to evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome. The

DSMB will make recommendations to the funder and the PIs concerning the continuation, modification, or conclusion of the trial. The DSMB will review the informed consent and make recommendations on any changes to the protocol. During the 18-month trial period, the DSMB will meet each quarter to review these data.

Harms: We used the SPRINT trial[4] adverse events (hypotension, dizziness, ED visits, acute kidney injury) for our study adverse events and provided an alert for when these are detected in the EHR to the study team, the patient, and the care team. Risks to participants include: 1) known adverse events from increased treatment and lowered BP, 2) psychological harm, and 3) loss of confidentiality. The adverse events are those common with medical and non-medical treatment of high BP and will be monitored by their primary care clinician.

Auditing: This study uses a single IRB through the University of Missouri-Columbia, #2091483.

Discussion

The Collaboration Oriented Approach to Controlling High BP (COACH) trial intends to understand how BP control can be improved by increasing adherence to patient-facing guideline-based recommendations. The focus of the trial is on home BP monitoring, as the starting recommendation underscores the key aspect of home-based efforts to assess and self-manage BP. The intervention also "closes the loop" between patient home monitoring, and getting patient data to the care team in a way that provides actionable information for hypertension management designed to fit the care team preferred workflows and management goals. The intervention, an enhanced version of COACH that includes BP data visualization, affectively enhanced visual summaries, and reminders about BP management, is based on core principles of Social Cognitive Theory, including self-efficacy, social support, outcome expectations, and self-regulation[32, 45-49]. The underlying premise is that higher affective alerting will increase accuracy in judgments about hypertension control and risk

perception and motivate patients out of goal range to appropriate action, without creating excess anxiety, which will allow safe, efficient and effective behavioral and medication changes[32, 50-52].

There have been several other trials that address home BP monitoring. Bosworth et al.[53, 54] showed that nurse-based telephone support coupled with home BP monitoring was more effective for BP control than usual care or telephone support alone. This effect was strongest for non-white patients. However, individual team-based coaching support is expensive and challenging to scale. Mobile health applications have shown promise in providing this support for key populations, including those with high BP, showing a -4.1 mmHg drop in SBP in a systematic review[20]. These trials generally depend on revised systems of care to enhance patient engagement, with the digital tool a part of the overall intervention COACH is designed to be a scalable electronic patient- and care team-facing intervention that does not require additional personnel to implement.

This trial intends to test whether a more advanced, tailored digital intervention can overcome these barriers in a pragmatic way – in essence, with minimal care redesign. To accomplish this goal, we leverage **Social Cognitive Theory (SCT)** to drive improved patient engagement to measure BPs and accomplish goals for BP lowering. We incorporate these principles along with tailored messaging informed by decision psychology into the intervention to drive engagement and uptake.

We also adapted the trial design based on substantial pre-implementation evaluation. To increase the likelihood of generalizable evidence from the trial, we performed a multimodal qualitative study. Results from the analysis were used to: 1) offer ad hoc and population-based referral techniques that matched high BP quality improvement initiatives in the practices; 2) change the intervention itself to ensure care teams were getting the information they needed; 3) identify additional personnel that participate in BP management, including pharmacists, panel coordinators, and medical assistants; and 4) ensure we had good bi-directional communication with the practices. Our implementation blueprint incorporates these elements and will be useful

for researchers looking to implement studies that interdigitate with clinic workflow and minimize burden while maximizing benefit.

This trial is timely. Information exchange standards and regulations are advancing our ability to create highly functional digital interventions that can integrate directly into care. The 21st Century Cures Act and related regulations require healthcare organizations to release information to patients using relevant standards without extra effort. The COACH tool uses these standards (FHIR) to build a comprehensive and tailored tool that can incorporate specific patient contexts, overcoming previous gaps and enabling easier guidance. Our previous work showed that the available data through the EHR FHIR server was not sufficient to use standard guideline recommendations without adaptations needed to consider missing and inaccurate data;[24] these adaptations may help expand available data since we are exchanging data back to the EHR.

The results of this trial will help to understand how engagement with digital interventions can be enhanced with affective alerts and other design changes; and whether these changes can help lower blood pressure in a pragmatic way through home monitoring. The flexibility of the tool, its adherence to standards, and its incorporation into a carefully designed implementation blueprint to fit into the workflow will be helpful to future researchers and innovators. In addition, the explicit goal of placing minimal burden on care teams and engaging patients in achieving safe and effective BP control is likely to generate knowledge useful about how to optimally redesign primary care processes.

Ethics and Dissemination

Research ethics approval: Single IRB oversight through the University of Missouri-Columbia IRB, #2091483.

Protocol amendments: Key Study Personnel (KSP) plan to communicate important protocol modifications (e.g, changes to eligibility criteria, outcomes, analyses) to the appropriate parties (e.g, IRB, trial participants, DSMB).

Competing Interests: No, there are no competing interests for any author.

Consent and assent: KSP will obtain informed consent from potential trial participants through an electronic tool called REDCap.

Confidentiality: The Principal Investigators (PI) will be responsible for ensuring participants' privacy, confidentiality, and data security. Data collection via REDCap will enhance data security. All data will be stored on secure encrypted, HIPAA compliant, SharePoint/OneDrive securely. COACH access has been strategically nested within the 3 sites' EHRs/patient portals to eliminate additional sign-ons and exposure to data threats. The Data and Safety Monitoring Board (DSMB) will review any instances of loss of confidentiality and will review adverse events that meet the reporting requirements. The DSMB will make recommendations to AHRQ and the PIs concerning the continuation, modification, or conclusion of the trial.

Ancillary and post-trial care: Care will always be directed by the care team, and the use of the tool or similar functions will be available after the trial is over.

Funding: The Agency for Healthcare Research and Quality (AHRQ) - R18HS028579

Dissemination policy: Trial results and the implementation details, including the logic and concepts from COACH, will be made available via publications, on Clinicaltrials.gov, and via open source mechanisms[27, 55].

Data Availability Statement: Not Applicable

Contributorship statement: DD, RK, AR, SC, VS, and WM collectively planned the study, collaborated on grant writing, and jointly drafted and reviewed this manuscript. VS conducted Qualtrics studies to gather feedback on the study components. EM and PG, acting as study coordinators at the Missouri site, facilitated study submissions, leveraging Missouri's role as the single IRB. They played integral roles in manuscript drafting and review. AG, the study coordinator at the Oregon site, contributed to the creation of site-specific documents and educational materials within the COACH application, in addition to drafting and reviewing the manuscript. LM established the REDCap survey database, significantly contributed to manuscript editing, and serves as the program manager for the study. BJ and ML, serving as patient co-investigators, provided valuable feedback on recruitment materials, the COACH interface, and overall study design. Authors affiliated with the COACH Consortium meet the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE). EC provided project administration. AY contributed to software development, validation, and visualization. MB engaged in data curation, software development, supervision, validation, and visualization for the COACH application. DC supported the conceptualization of the study, contributed to visualization, writing, and manuscript review, and serves as a member of the COACH advisory board. JS assisted with project administration at one of the clinics and provided resources essential for successful implementation. GF contributed to COACH methodology, software development, manuscript writing and review, and also serves on the COACH Advisory Board. KP aided in project administration at one of the clinics and participated in manuscript review. JP contributed to methodology, manuscript writing, and review. MS served as an engineer on the COACH team, assisting with software development. SM served as the statistician, contributing to formal analysis, visualization, initial manuscript drafting, and review.

Appendices

Appendix 1. CFIR Semi-Structured Interview Guide

Appendix 2. Patient Focus Group Guide
Appendix 3. Informed consent materials

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Table 1. RE-AIM measures and outcomes

RE-AIM Evaluation Measures		
Component	**Outcome Measures**	**Source**
Reach		
1. Number of eligible enrolled patients	CONSORT	REDCap - baseline survey
2. Differences from the eligible population	CONSORT	REDCap - baseline survey
Effectiveness		
1. Intervention effects on outcome	Primary	Electronic Health Record, patient portal
	Secondary	Electronic Health Record, patient portal
2. Increase in patient:	Social Cognitive Theory	Patient 2/6 month follow up survey
Adoption		
1. Number of Home BP recordings entered	Counts	Electronic Health Record, patient portal
2. Number of encountered study blocks	App usage	Electronic Health Record, patient portal
Implementation		
1. Number of portal/phone messages about BP during 6-month intervention period		Electronic Health Record, patient portal
2. Barriers to Implementation	Interviews	CFIR Evaluation
3. Increased/decreased burden of intervention	Interviews	CFIR Evaluation
4. physician/nurse/patient suggestions	Interviews	CFIR Evaluation
5. participant support needs	Email, phone outreach to study staff	REDCap ongoing events
Maintenance		
1. Number of patients who continue to use the app and BP cuff		Study Participant Tracking
2. Institutional use of tools beyond trial		CFIR Evaluation

Table 2. COACH Study Visit Schedule

Procedure	Baseline	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8	Week 24
Information Sheet, Consent, Screening, randomization	X							
Receive COACH related Instructions/materials	X							
Monitoring Block (2-4 Weeks)			If Needed post 2 weeks					
Goal Setting Block (1-2 Weeks)			If Monitoring block ends in 2 weeks		If monitoring block ends in more than 2 weeks			
Health Belief Survey	X							
Digital and Health Literacy	X							
UTAUT							X	X
REDCap Alerts								
REDCap Alerts (Control)								
AE Form*							X	X

*AE form continuously available

Figure Captions:

Figure 1: PRagmatic Explanatory Continuum Indicator Summary Tool-2 (PRECIS) Diagram

Figure 2a: COACH home page for enhanced arm; 2b: COACH home page for control arm

Figure 3: High BP warning (similar for low BP) for both groups

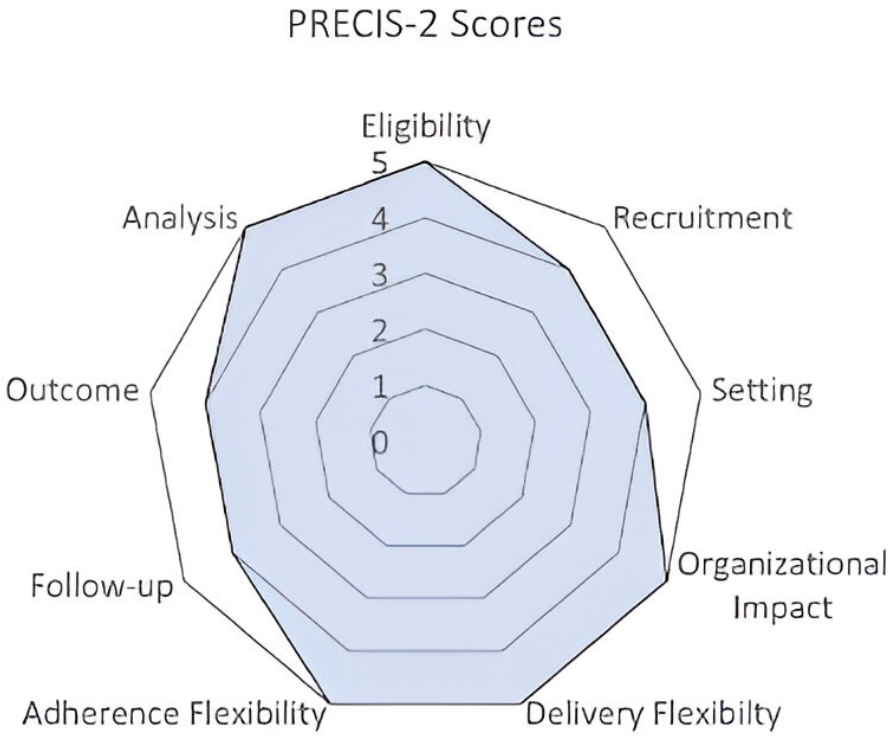

Figure 1: PRagmatic Explanatory Continuum Indicator Summary Tool-2 (PRECIS) Diagram

298x251mm (72 x 72 DPI)

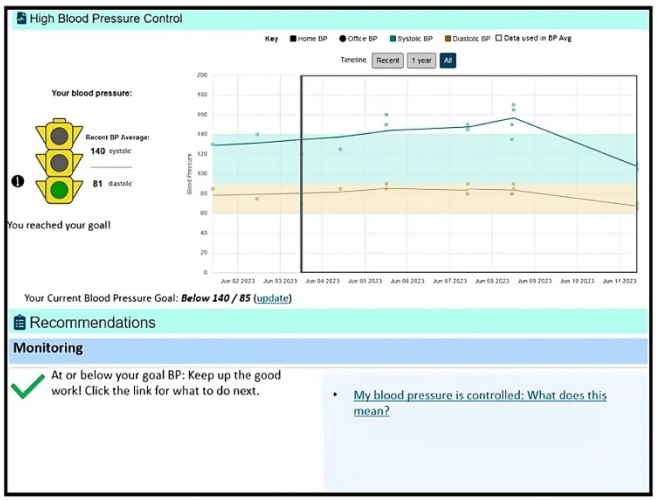

Figure 2a: Home page for enhanced arm COACH

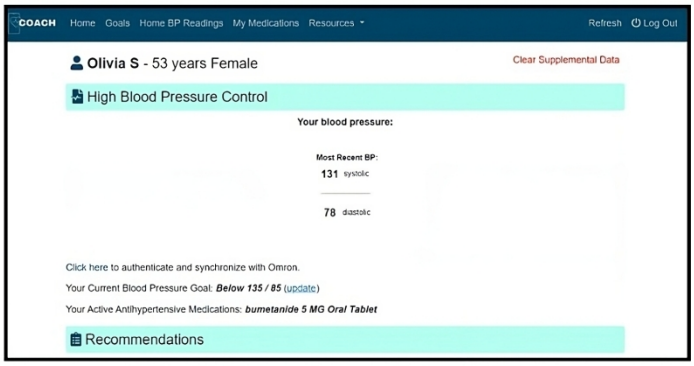

Figure 2b: Home page for control arm COACH

Figure 2a: COACH home page for enhanced arm; 2b: COACH home page for control arm

762x762mm (72 x 72 DPI)

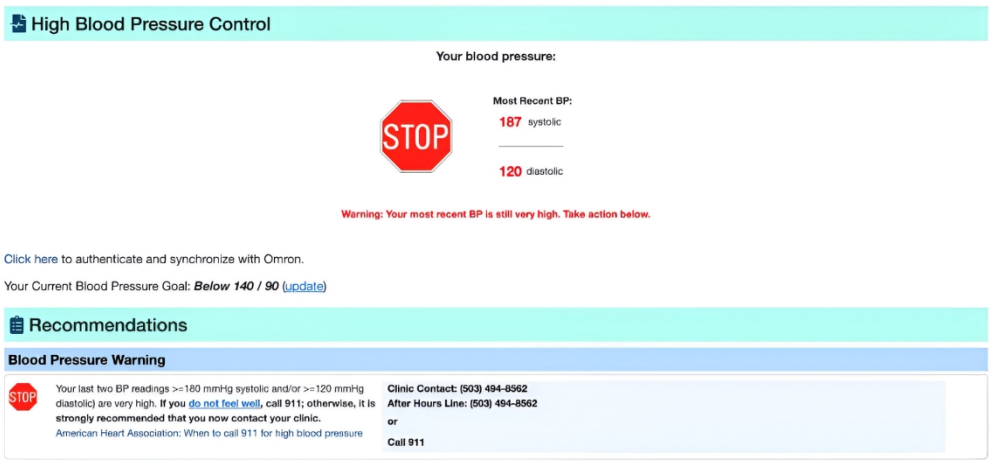

Figure 3: High BP warning (similar for low BP) for both groups

776x363mm (72 x 72 DPI)

Implementation of COACH: Semi-Structured Interview Guide

Notes to interviewer:

1. All questions will not be relevant for all stakeholders and will vary depending on the stage of implementation. Tailor questions by deleting questions that do not apply to stakeholder/stage – it is likely that more than half will be deleted for an appropriate interview of reasonable length)
2. The intervention = the COACH decision support tool to support patients in self-managing blood pressure, home blood pressure, and cardiovascular disease risk

Evidence Strength & Quality

1. What kind of supporting evidence or proof is needed about the effectiveness of the intervention to get staff on board?
    - Co-workers? Administrative leaders?

Relative Advantage

1. Is there another intervention that people would rather implement?
    - Can you describe that intervention?
    - Why would people prefer the alternative?

Adaptability

1. What kinds of changes or alterations do you think you will need to make to the intervention so it will work effectively in your setting?
    - Do you think you will be able to make these changes? Why or why not?
2. Who will decide (or what is the process for deciding) whether changes are needed to the intervention so that it works well in your setting?
    - How will you know if it is appropriate to make any changes?
3. Are there components that should not be altered?
    - Which ones should not be altered?

Trialability

1. Will the intervention be piloted prior to full-scale implementation?
    - [If Yes] Can you describe what your plans are for piloting the intervention?
    - [If Yes] What will the pilot look like?
2. Do you think it would be possible to pilot the intervention before making it available to everyone?
    - Why or why not?
    - Would this be helpful?

Complexity

1. How complicated is the intervention?
    - Please consider the following aspects of the intervention: duration, scope, intricacy and number of steps involved and whether the intervention reflects a clear departure from previous practices.

Design Quality & Packaging

1. What is your perception of the quality of the supporting materials, packaging, and bundling of the intervention for implementation?
    - Why?
2. What supports, such as online resources, marketing materials, or a toolkit, are available to help you implement and use the intervention?
    - How do you access these materials?
3. How will available materials affect implementation in your setting?

Cost

1. What costs will be incurred to implement the intervention?

Patient Needs & Resources

1. To what extent were the needs and preferences of the individuals served by your organization considered when deciding to implement the intervention?
    - Can you describe specific examples?
    - Will the intervention be altered to meet their needs and preferences?
2. How well do you think the intervention will meet the needs of the individuals served by your organization?
    - In what ways will the intervention meet their needs? E.g. improved access to services? Reduced wait times? Help with self-management? Reduced travel time and expense?
3. How do you think the individuals served by your organization will respond to the intervention?
4. What barriers will the individuals served by your organization face to participating in the intervention?
5. Have you heard stories about the experiences of participants with the intervention?
    - Can you describe a specific story?

Peer Pressure

1. Can you tell me what you know about any other organizations that have implemented the intervention or other similar programs?
    - How has this information influenced the decision to implement the intervention?
2. To what extent are other units within your organization implementing the intervention?
    - How does that affect support for implementing the intervention in your own setting?
3. To what extent would implementing the intervention provide an advantage for your organization compared to other organizations in your area?
    - Is there a competitive advantage?
    - Is there something about the intervention that would bring more individuals into your organization, instead of another one in your area?

External Policies & Incentives

1. What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced the decision to implement the intervention?
    - How will the intervention affect your organization's ability to meet these measures, policies, regulations, or guidelines?
2. What kind of financial or other incentives influenced the decision to implement the intervention?

- How will the intervention affect your organization's ability to receive these incentives?
- How will the new intervention affect payment or revenue for your organization?

Structural Characteristics

1. How will the infrastructure of your organization (social architecture, age, maturity, size, or physical layout) affect the implementation of the intervention?
   - How will the infrastructure facilitate/hinder implementation of the intervention?
   - How will you work around structural challenges?
2. What kinds of infrastructure changes will be needed to accommodate the intervention?
   - Changes in scope of practice? Changes in formal policies? Changes in information systems or electronic records systems? Other?
   - What kind of approvals will be needed? Who will need to be involved?
   - Can you describe the process that will be needed to make these changes?

Networks & Communications

1. Can you describe your working relationship with influential stakeholders?
2. Are meetings, such as staff meetings, held regularly?
   - Do you typically attend?
   - Who typically attends?
   - What proportion of staff typically attend?
   - How often are the meetings held?
   - What is a typical agenda? How helpful are these meetings?
3. How do you typically find out about new information, such as new initiatives, accomplishments, issues, new staff, staff departures?
4. When you need to get something done or to solve a problem, who are your "go-to" people?
   - Can you describe a recent example?

Culture

1. How would you describe the culture of your organization? Of your own setting or unit?
   - Do you feel like the culture of your own unit is different from the overall organization? In what ways?
2. How do you think your organization's culture (general beliefs, values, assumptions that people embrace) will affect the implementation of the intervention?
   - Can you describe an example that highlights this?
3. To what extent are new ideas embraced and used to make improvements in your organization?
   - Can you describe a recent example?
4. *This question can be open-ended or elicit percentages so that they add up to 100%. e.g., my culture is 50% Team, 40% entrepreneurial, 10% hierarchical.*

   Some people characterize culture in terms of four general types. To what extent would you characterize your culture as:

   - Team (Clan) Culture (Flexible, Internal Focus): A friendly workplace where leaders act like mentors, facilitators, and team-builders. There is value placed on long-term development and doing things together.

- Hierarchical (Hierarchy) Culture (Control, Internal Focus): A structured and formalized workplace where leaders act like coordinators, monitors, and organizers. There is value placed on incremental change and doing things right.
- Entrepreneurial (Adhocracy) Culture (Flexible, External Focus): A dynamic workplace with leaders that stimulate intervention. There is value placed on breakthroughs and doing things first.
- Rational (Market) Culture (Control, External Focus): A competitive workplace with leaders like hard drivers, producers, or competitors. There is value placed on short-term performance and doing things fast.

Implementation Climate

1. *This question is likely to uncover topics to explore more within other sub-constructs, but be attentive to other themes that may not be included in your assessment.*

   What is the general level of receptivity in your organization to implementing the intervention?

   - Why?

Tension for Change

1. Is there a strong need for this intervention?
   - Why or why not?
   - Do others see a need for the intervention?
2. How essential is this intervention to meet the needs of the individuals served by your organization or other organizational goals and objectives?
3. How do people feel about current programs/practices/process that are available related to the intervention?
   - To what extent do current programs fail to meet existing needs? Will the intervention meet these needs?
   - How will the intervention fill current gaps?

Compatibility

1. How well does the intervention fit with your values and norms and the values and norms within the organization?
   - Values relating to interacting with individuals served by your organization, e.g. shared-decision making vs. being more directive?
   - Values related to referring to outside vendor-based programs vs. providing services by in-house staff?
2. How well does the intervention fit with existing work processes and practices in your setting?
   - What are likely issues or complications that may arise?

Relative Priority

1. Describe activities or initiatives that (appear to) have highest priority for you (for the organization)?
   - What kind of pressure are you feeling to accomplish this? Where is it coming from? Why?
2. To what extent might the implementation take a backseat to other high-priority initiatives going on now?
   - How important do you think it is to implement the intervention compared to the other priorities?

- How important is it to others, such as your coworkers or leaders, to implement the intervention compared to the other priorities?

3. How will you juggle competing priorities in your own work? How will your colleagues juggle these priorities?
   - What are the other priorities?
   - How does the priority of implementing the intervention compare to other priorities in your organization? For your own work?

Organizational Incentives & Rewards

1. What kinds of incentives are there to help ensure that the implementation of the intervention is successful?
   - What is your motivation for wanting to help ensure the implementation is successful?
2. Are there any special recognitions or rewards planned that are related to implementing the intervention?
   - Can you describe them?
   - Will these be targeted to groups/teams/units or individuals?

Goals & Feedback

1. To what extent are organizational goals monitored for progress?
   - Can you give an example of monitoring in terms of the type of information, who is informed, and how?
2. Do you get any feedback reports about your work?
   - What do they look like? Content, mode, form?
   - How helpful are those reports?
   - How can they be improved?
   - How often do you get them? Where do they come from?
   - Who designed them?
3. *This question can be framed in terms of the intervention. For example, in a healthcare setting: How does implementation of the intervention align with organizational goals related to preventing*

   How does implementation of the intervention align with other organizational goals?

Learning Climate

1. Can you describe a recent quality improvement initiative or an implementation of a new program?
   - Can you describe the new initiative/program and the motivation to improve/implement it?
   - Can you tell me the major milestones or key accomplishments along the way?
   - What factors helped make it successful/fail?
   - Who were the key "players"?
   - What was your involvement?
   - Were people happy with the outcome/initiative?
   - Can you tell me about how leaders were involved? Who? Their roles? How they helped/hindered?
2. If you saw a problem in your own setting, what would you do?
   - Can you tell a story about a recent problem you resolved or initiative you participated in?
3. To what extent do you feel like you can try new things to improve your work processes?

- Do you feel like you have the time and energy to think about ways to improve things?
- Did you feel valued/respected by your supervisor for the role you played?
- What role did your supervisor (or other leaders) play? What actions did they take?

Readiness for Implementation

Leadership Engagement

1. What level of involvement has leadership at your organization had so far with the intervention?
   - Do they know about the intention to implement the intervention?
   - Who are these leaders? How do attitudes of different leaders vary?
   - What kind of support have they given you? Can you provide specific examples?
2. What kind of support or actions can you expect from leaders in your organization to help make implementation successful?
   - Who are these leaders? How do attitudes of different leaders vary?
   - Do they know about the intention to implement the intervention?
   - What kind of support can you expect going forward? Can you provide specific examples?
   - What types of barriers might they create?

Available Resources

1. Do you expect to have sufficient resources to implement and administer the intervention?
   - [If Yes] What resources are you counting on? Are there any other resources that you received, or would have liked to receive?
   - What resources will be easy to procure?
   - [If no] What resources will not be available?
2. How do you expect to procure necessary resources?
   - Who will be involved in helping you get what is needed?
   - What challenges do you expect to encounter?

Access to Knowledge & Information

1. What kinds of information and materials about the intervention have already been made available to you?
   - Copies of materials?
   - Personal contact?
   - Internal information sharing; e.g., staff meetings?
   - Has it been timely? Relevant? Sufficient?
2. *This question may also be relevant to Engaging: Key Stakeholders.*

   What kinds of information and materials about the intervention are planned for individuals in your setting?

   - Copies of materials?
   - Personal contact?
   - Internal information sharing; e.g., staff meetings?
   - Will it be timely? Relevant? Sufficient?

Knowledge & Beliefs about the Intervention

1. What do you know about the intervention or its implementation?
2. Do you think the intervention will be effective in your setting?
    - Why or why not?
3. How do you feel about the intervention being used in your setting?
    - How do you feel about the plan to implement the intervention in your setting?
    - Do you have any feelings of anticipation? Stress? Enthusiasm? Why?

Self-efficacy

1. How confident are you that you will be able to use the intervention?
    - What gives you that level of confidence (or lack of confidence)?
2. How confident do you think your colleagues feel about using the intervention?
    - What gives them that level of confidence (or lack of confidence)?

Individual Stage of Change

1. *Explore which level the individual is at using Rogers' (or Porchaska's Stages of Change) as a guide:*

    How prepared are you to use the intervention?

    - Knowledge stage (Precontemplation) - knowledge of key aspects of the intervention
    - Persuasion stage (Contemplation) - likes the intervention, discusses it with others, buys into it, has a positive view
    - Decision stage (Preparation) - intends to seek additional information and try it
    - Implementation stage (Action) - acquires additional information, uses intervention regularly, and has continued use
    - Confirmation stage (Maintenance) - recognizes benefits, has integrated the intervention into routines, promotes use to others

Individual Identification with Organization

- *Responses to other questions may be (double) coded here. For example, buy-in to organizational or intervention-related goals may be elicited under Goals & Feedback, but may also be relevant here.*

Other Personal Attributes

- *The type of statements coded here will depend on study objectives, for example, locus of control, and other concepts from health or organizational psychology found to be related to a particular implementation.*

Planning

1. Can you describe the plan for implementing the intervention?
    - How detailed is the plan? Who knows about it? Is the plan overly complex? Understandable? Realistic and feasible?
    - What is your role in the planning process?
    - Who is involved in the planning process? What are their roles?
    - Are the appropriate people involved in the planning process? How engaged are they?

- Do you plan to track the progress of implementation based on your plan?
- What if you have to modify or revise your plan due to barrier, errors, or mistakes?

Engaging

Opinion Leaders

1. Who are the key influential individuals to get on board with this implementation?
2. What are influential individuals saying about the intervention?
   - Who are these influential individuals?
   - To what extent will they influence others' use of the intervention? The success of the implementation?

Champions

1. Other than the formal implementation leader, are there people in your organization who are likely to champion (go above and beyond what might be expected) the intervention?
   - Were they formally appointed in this position, or was it an informal role?
   - What position do these champions have in your organization?
   - How do you think they will help with implementation? Getting people to use the intervention?
2. What kinds of behaviors or actions do you think this individual/champion will exhibit?
   - For example, helping get senior leaders on board, helping solve problems? Or a small role?

Key Stakeholders

1. What is your communication or education strategy (not including training, see Access to Knowledge and Information) for getting the word out about the intervention?
   - What materials/modes/venues do you plan to use? For example e-bulletin boards, emails, brochures?
   - What process do you plan to use to communicate? For example, going to staff meetings, talking to people informally?
2. Who are the key individuals to get on board with the intervention?
   - To encourage individuals to use the intervention? To help with implementation?

Intervention Participants

1. How will you or your colleagues communicate to the individuals that are served by your organization about the intervention?
   - How will they participate in the intervention?
   - How will they access the intervention?

Executing

1. Has the intervention been implemented according to the implementation plan?
   - [If Yes] Can you describe this?
   - [If No] Why not?

Reflecting & Evaluating

1. What kind of information do you plan to collect as you implement the intervention?
   - Which measures will you track? How will you track them?

- How will this information be used?

2. Will you receive feedback reports about the implementation or the intervention itself?
   - What will they look like? Content, mode, form?
   - How helpful do you think they will be?
   - How could they be improved?
   - How often will you get them? Where will they come from?
   - Who is designing them?
3. How will you assess progress towards implementation or intervention goals?
   - How will results of the evaluation be distributed to stakeholders?
4. Will feedback be elicited from staff? From the individuals served by your organization?
   - [If yes] What kind of feedback?
5. To what extent has your organization/unit set goals for implementing the intervention?
   - How will goals be communicated in the organization? To whom will they be communicated?
   - What are the goals? How and to whom will they be communicated?

Focus group 1 - guide for patients with hypertension and high blood pressure

[Introduction- to be read at the beginning of each focus group]
Thank you again for agreeing to participate in our study. What we plan to do today is to ask you some questions about COACH and how we can engage you and other patients with high blood pressure or hypertension, and if COACH can meet the informational needs of self-monitoring and self-management of high blood pressure. But before we get started, I'd like to go over a few "ground" rules:

- We would like to hear from each of you. So, we hope all of you will join in the discussion and share your thoughts. We know that some people find it easier to talk in a group than others. So, please be mindful and "share the air."
- These sessions will be recorded, and later the recordings will be transcribed. We will not identify you on our transcripts. Your name and contact information will be kept in a separate database. We discussed this as part of our consent process, but before we move forward, we would like to ensure everyone is comfortable with this.
- Because we are recording, we ask that everyone take turns speaking. Otherwise, it will be very difficult to hear what you are saying making it difficult to transcribe later on. Also, please make sure to speak up, so that we can hear you on the recording.
- There are no right or wrong answers. So, please feel free to disagree or share a different perspective. We know you will all keep a respectful tone.
- We are asking everyone to be candid about their thoughts. However, we also request that you keep what is said here confidential in order to respect everyone's privacy (including your own).
- Before we get started, does anyone have any questions?

Focus Group 1

Presenting the prototype screens (comments/questions for each of the screens, video, or overall) of application COACH (if there is one already)

- What is your experience with telemonitoring (MyChart/Health Connect) of your blood pressure, or other medical conditions?
    - Pros? Cons? Challenges?
- How does your doctor usually communicate with you about your most recent BP measurement?
    - In what type of clinical situations is communication more likely? (e.g., medication or dose change, symptoms of low BP, side effects, etc.)
    - During a visit vs. between visits?
- How does home monitoring of your blood pressure make you feel, regarding managing your hypertension ?
- Do you know when and how to contact your healthcare team to seek help regarding your BP?
    - Could something like COACH help you with this? If so, how?
- What concerns do you have about managing your own BP at home?
    - Is there anything that would keep you from doing this?

- What helps you (or would help you) do this?
- Why/when might you not do this?

- What do you think you would need in terms of support/resources (like gamification) for you to continue to measure your BP at home? For example, education, encouraging texts/portal messages, etc.?
- What is your understanding of the "COACH" EHR visualization tool?
  - What are your initial thoughts on the "COACH" EHR visualization tool?
  - Would you use a tool like this? Why or why not?
  - In what situations do you think COACH would be most helpful? (e.g., medication change, managing/tracking improvements in habits and lifestyle?
- How would you prefer to receive feedback about entered home BP values/COACH activities?
  - What format of obtaining feedback on entered home BP values would you prefer? For example, telemonitoring, paper, or text? Why?
  - From whom would you find it valuable to receive feedback? Doctor, nurse, other member of care team, algorithmic or AI?
- Do you like the idea of setting your own goals in COACH? What do you think about customization of goals as per individual patient being integrated into COACH?
- Describe how you would prefer your medication history be presented in COACH?
- How often/when do you think you would you likely use COACH to self-monitor and self-manage your blood pressure in home?
- Do you think notifications/alerts would be useful tools to remind you to monitor your BP? Is so, what sorts of alerts would you prefer to receive (text messages, pop-up messages, etc., and how often would you want them? Describe what you feel you would need in terms of notifications/alerts in COACH, and how do you feel these notifications/alerts might be useful in terms of reminding you to monitor your BP?
- How can we make this experience better for you using COACH to self-monitor your BP? Do you have enough information/guidance to do so, etc.?

IRB # STUDY00024520

CLINICAL RESEARCH CONSENT AND AUTHORIZATION
SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Collaboration Oriented Approach to Controlling High Blood Pressure (COACH)

PRINCIPAL INVESTIGATORS: Richelle Koopman, MD, MS (573) 882-0598
David Dorr, MD, MS (503) 418-2387

CO-INVESTIGATOR: William Martinez, MD, MSc (615) 322-3000

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not. This is a multi-site study with University of Missouri-Columbia (MU), Oregon Health & Sciences University (OHSU) and Vanderbilt University Medical Center (VUMC).

PURPOSE: The purpose of the study is to learn how well the COACH application can help lower blood pressure. We are hoping to find out ways to help people manage high blood pressure.

DURATION: Your participation in the study will consist of three surveys over 6 months and blood pressure monitoring from home. Surveys will last up to 20 minutes each.

PROCEDURES: If you decide to participate, you will be asked to complete surveys now, in 8 weeks and in 6 months. You will also be asked to use the COACH application and to monitor your blood pressure during those 6 months.

RISKS: The main risk is a loss of confidentiality. You may also feel side effects that are common during blood pressure management.

BENEFITS: You may not directly benefit from taking part in this research. The COACH application may help you reduce your blood pressure.

ALTERNATIVES: You may choose not to participate in this study, may receive standard blood pressure treatment or participate in another study if one is available.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Study Team if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

IRB # STUDY00024520

Research Consent and Authorization Form

PROJECT TITLE: Collaboration Oriented Approach to Controlling High Blood Pressure (COACH)

PRINCIPAL INVESTIGATORS: Richelle Koopman, MD, MS (573) 882-0598
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This is a multi-site study with University of Missouri- Columbia (MU), Oregon Health & Sciences University (OHSU) and Vanderbilt University Medical Center (VUMC).

CONTACT INFORMATION:

Email: COACH-OHSU@ohsu.edu
Phone: 833-462-9191

WHO IS PAYING FOR THE STUDY? *Agency for Healthcare Research and Quality (AHRQ)*

WHO IS PROVIDING SUPPORT FOR THE STUDY? *None*

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY? *No*

WHY IS THIS STUDY BEING DONE?

You have been invited to be in this research study because you have high blood pressure and your clinician or care team recommend that you participate in a home blood pressure monitoring program. The purpose of this study is to evaluate the effectiveness of the COACH application to lower blood pressure using evidence-based research and patient participation to maximize effectiveness.

A total of 550 patients will be enrolled into the study. Patients are asked to participate in this study for 6 months. You will be asked to monitor your blood pressure using the COACH application and complete surveys.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

In addition to your regular blood pressure management regiment, you will use the COACH web-based application to measure your blood pressure regularly. You will be provided a link that directs you to instructions on how to use the COACH application. You will be asked to measure your blood pressure regularly from your home. We will provide you with a blood pressure cuff with Bluetooth connection to use at home and record your results in COACH. You will receive information about your blood pressure readings and may receive additional recommendations. Your health record information including medications and blood pressure will be accessed by COACH.

You will complete surveys at three time points. The surveys will ask questions about how you manage your health and your experience using the COACH application.

Below is a breakdown of study procedures you may expect to complete as a participant in this study:

	Baseline Day 1	Week 8 (2 months)	Week 24 (6 months)
Consent Discussion, Screening questions and Survey #1	X		
Receive information on how to use COACH	X		
Survey #2		X	
Survey #3			X
Study payment for completing survey #3			X
Total time	30-60 minutes	20-25 minutes	20-25 minutes

WILL I RECEIVE RESULTS FROM THE STUDY?
You will not receive results from this study. However, your care team will be notified when your blood pressure is high (>180mmHg/120mmHg) or low (<90mmHg/60mmHg).

If you are interested in staying informed about the progress being made on the development of the application, and continuing to contribute to the development process, we may ask for your permission to contact you again in the future.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?
Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. You may also experience some side effects commonly experienced when people manage their blood pressure could include dizziness.

PERMISSION TO USE YOUR PROTECTED HEALTH INFORMATION:
State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.

You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

In this study we will take steps to keep your personal information confidential, but we cannot guarantee total privacy. We will be deidentifying information for data analysis.

Some identifiers about you will be obtained from your health records and are necessary for this research. The identifiers will include your name, address, dates related to you, phone numbers, email addresses, medical record number, social security number.

We may have to release this information to others for example, if the study is audited. However, we would try to do so without information that could identify you. This release could be to the Institutional Review Board (ethics review committee) overseeing the study at the University of Missouri, the Agency for Healthcare Research and Quality, or Office of Human Research Protection (agencies that oversee research). Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.

We may continue to use and disclose your information as described above indefinitely to disseminate research findings and results.

Some of the information collected and created in this study may be placed in your medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your medical record. If you have questions about what study information you will be able to access, and when, ask the study team.

After you join the study, you can choose to receive all future survey links and reminders by text message. If you choose this option, you are giving us permission to share your phone number with our vendor Twilio Inc. to send you these text messages.

We will limit the content of the text messages to general information such as survey links and reminders to complete your survey. Even so, these messages may contain information that you wish to keep confidential. Text messaging is not encrypted, messages can be intercepted by others, viewed by people who see your phone or sent to the wrong person, and may not be confidential.

If, at any point, you no longer wish to receive text messages from the study team, tell us by sending an email to COACH-OHSU@ohsu.edu or calling this number 1-833-462-9191, and we will stop sending you text messages.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no cost to you or your insurance company to participate in this study. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your medical condition. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

If you remain in the study and complete the final survey at 24 weeks (6 months), you will receive a $20 payment via electronic gift card. The gift card will be delivered via email and you will have an option to choose between Amazon, Walmart or Target.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact **COACH-OHSU@ohsu.edu**.

If you are injured or harmed by the study procedures, you will be treated. Any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

WHERE CAN I GET MORE INFORMATION?

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Richelle Koopman at koopmanr@health.missouri.edu or other members of the study team at COACH-OHSU@ohsu.edu. or call 833-462-9191.

If you have questions about your rights as a research participant, please contact the MU Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?

As a participant in this study we will ask you to monitor you blood pressure regularly and record it in the COACH application. We will also ask you to complete surveys at three time points during the study.

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the study team if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

COACH Coordinator: COACH-OHSU@ohsu.edu (one email for all 3 sites)

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

The information that we will collect from you will not be stored with your name or any other identifier. Therefore, there will not be a way for us to identify and destroy your materials if you decide in the future that you do not wish to participate in this research.

You may be removed from the study if the investigator or funder stops the study, your primary care provider believes it is not safe for you to continue with the study, or if you meet the exclusion criteria after signing this consent document.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study. We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
	6b	Explanation for choice of comparators	n/a
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	15
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	17
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	18
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	18
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.