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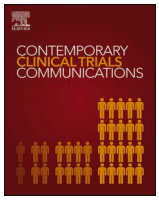

# Recruitment and retention of primary care practices in the Southeastern Collaboration to Improve Blood Pressure Control

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ABSTRACT

*Background:* Racial disparities related to hypertension prevalence and control persist, with Black persons continuing to have both high prevalence and suboptimal control. The Black Belt region of the US Southeast is characterized by multiple critical priority populations: rural, low-income, and minority (Black).

*Methods:* In a cluster-randomized, controlled, pragmatic implementation trial, the Southeastern Collaboration to Improve Blood Pressure Control evaluated two multi-component, multi-level functional interventions – peer coaching (PC) and practice facilitation (PF) (separately and combined) – as adjuncts to usual care to improve blood pressure control in the Black Belt. The overall goal was to randomize 80 primary care practices (later reduced to 69 practices) in Alabama and North Carolina to one of four interventions: 1) enhanced usual care (EUC); 2) EUC plus PC; 3) EUC plus PF; or 4) EUC plus both PC and PF. Several measures to facilitate recruitment and retention of practices were employed, including practice readiness assessment.

*Results:* Contact was initiated with 248 practices during the study enrollment period. Of these, 99 declined participation, 39 were ineligible, and 41 were being evaluated for inclusion when the target number of practices was reached. The remaining 69 practices eventually were enrolled, with 18 practices randomized to EUC, 19 to PC, 16 to PF, and 16 to PC plus PF. Only two practices (2.9%) were withdrawn during the study. Several facilitators of and barriers to practice recruitment and retention were identified.

*Conclusion:* Our findings underscore the importance of a structured approach to recruiting primary care practices in a pragmatic implementation trial.

ClinicalTrials.gov registration number NCT02866669

## 1. Introduction

Racial disparities in cardiovascular disease (CVD) persist in the 21st century, with some of the most persistent disparities related to hypertension (HTN) prevalence and control. Non-Hispanic Black (hereafter "Black") persons have among the highest prevalence of HTN in the US, and although Black persons are consistently more likely to be aware of their HTN and are more likely to be treated, they continue to have suboptimal control [1].

The regions of the US with the highest prevalence of HTN are in the Southeast, overlapping to a high degree with the Black Belt, an agricultural rural region historically named for its rich black soil, now characterized by low education and income levels, a high prevalence of

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**Abbreviations**

| | |
|---|---|
| AHEC | Area Health Education Center |
| AL, | Alabama |
| BP | blood pressure |
| CVD | cardiovascular disease |
| ECU | East Carolina University |
| EHR | electronic health record |
| EUC | enhanced usual care |
| FQHC | Federally Qualified Health Center |
| FWA | Federal Wide Assurance |
| HTN | hypertension |
| IQR | interquartile range |
| iSOLVE | Integrated Solutions for Sustainable Fall Prevention |
| NC | North Carolina |
| NCQA | National Committee for Quality Assurance |
| ORIC | Organizational Readiness for Implementing Change |
| PALS | Patient Activated Learning System |
| PC | peer coaching |
| PCMH | Patient-Centered Medical Home |
| PF | practice facilitation |
| SEC | Southeastern Collaboration to Improve Blood Pressure Control |
| UAB | University of Alabama at Birmingham |
| UNC | University of North Carolina at Chapel Hill |

poverty, and a large population of Black persons. Distances between patients' residences and where they obtain primary care are great in this region, with many residents traveling an hour or more to see a health-care provider, potentially resulting in fewer visits and less monitoring of CVD risk factors, such as HTN [2]. HTN is highly prevalent among residents of this region, particularly among Black persons, and blood pressure (BP) control is suboptimal, resulting in a higher prevalence of HTN-related outcomes, including myocardial infarction, stroke, heart failure, end-stage renal disease, and premature mortality [1,3]. The Black Belt is therefore a region that has all critical priority populations: rural, low-income, and minority – a "triple threat" to health and longevity requiring innovative intervention strategies. Literature on recruitment and retention strategies in hypertension intervention studies of low-income Black patients is scarce. The few available published reports all indicated recruitment and retention challenges when working with this population, including comorbidities in older patients, conflicting patient work schedules, transportation barriers, major life events, and interpersonal conflicts [4].

The Southeastern Collaboration to Improve Blood Pressure Control (SEC) was a study led by investigators at the University of Alabama at Birmingham (UAB; Birmingham, Alabama [AL]), East Carolina University (ECU; Greenville, North Carolina [NC]), the University of North Carolina at Chapel Hill (UNC; Chapel Hill, NC), and Weill Cornell Medical Center (New York, NY). This large team explored different strategies to improve BP control in Black patients served by rural primary care practices in the Black Belt regions of AL and NC. The primary objective of the SEC was to address the "triple threat" by rigorously comparing the effectiveness of two practical approaches to achieving better BP – peer coaching (PC) and practice facilitation (PF) interventions – independently and combined, in primary care practices serving rural Southeastern Black patients with low socioeconomic status living in the Black Belt. The primary hypotheses were that each of the interventions would improve BP control more than enhanced usual care (EUC), and that the combined intervention would result in greater improvements in BP control than either intervention individually.

The interventions in the SEC were tested by recruiting and retaining at the practice level, rather than the patient level. Strategies to recruit primary care practices tested in previous studies include practice readiness assessment (assuring that a minimum standard is met prior to moving a practice forward to randomization) [5]; multiple interactions with the practice (including those by telephone, email, and in-person meetings) [6], identification of a practice champion (a point person within each practice for consistent communication about the project) [7]; and incentives (both monetary and resources) [8]. The goal of this report was to describe the application of these and other strategies to the recruitment and retention of primary care practices in the SEC, as well as facilitators of and barriers to practice recruitment and retention in this trial.

## 2. Methods

### 2.1. SEC: Overview

SEC was a cluster randomized, controlled, pragmatic implementation trial to evaluate EUC and two multi-component, multi-level functional interventions – separately and combined – as adjuncts to usual care to improve BP control. Specifically, the interventions entailed: 1) EUC, which consisted of a free online patient education program accessible to all patients and provision of a home BP monitoring device with instructions for use; 2) EUC plus PC services; 3) EUC plus PF services; and 4) EUC plus both PC and PF services.

### 2.2. Peer coaching services

The PC intervention entailed peer coaches working with patients to help them carry out the HTN treatment plan. This included providing patients with social and emotional support and encouragement to help them make behavior changes aimed at improving BP (e.g., consuming a healthier diet, increasing physical activity, taking antihypertensive medications as directed, checking BP at home, keeping medical appointments); linking patients with community resources (e.g., walking groups, farmers markets); working with practice staff to help patients understand instructions and encourage patients to alert staff to problems that arise (e.g., not being able to afford medications), and helping patients learn how to set achievable goals and track progress toward them. Peer coaches were trained and certified by SEC staff, lived and worked in the same communities as patients, had chronic medical conditions allowing them to empathize with patients and understand the day-to-day challenges of living with a chronic disease like HTN, but were not health professionals and did not provide medical advice. Peer coaches worked with patients over a 12-month period.

### 2.3. Practice facilitation services

PF is a highly customized, staged approach to helping a medical practice implement process and structural changes to enhance the quality of care – in this case BP control – and improve patient and staff satisfaction. The PF strategy helped practices transition from episode-based, reactive care to prevention of adverse health outcomes and population health management [9–12]. Key features included shifting the focus from single patients to populations, and from physician-centric to team-based clinical management. PF emphasizes self-management support and maximizing the use of electronic health record (EHR) data, including the creation of registries, audit and feedback programs, and outreach [13]. PF was a highly engaged, flexible consultative service designed to facilitate practice transformation and involved a practice facilitator – a person trained and certified in quality improvement techniques – visiting the practice regularly to teach the team approach

and fully utilize the potential of EHRs. Facilitators assisted the practice in assessing the practice, setting goals, and building capacity to gather data to create performance metrics. They also assisted the practice in monitoring its performance, mapping workflows, and implementing plan-do-study-act cycles to improve quality of care. The PF intervention incorporated approaches that had proven successful in improving quality in other practices; assisted practice personnel in assessing how well they were doing with specific populations of patients, such as the proportion of patients with HTN with adequate BP control; and assisted practice personnel in building skills to continue a data-driven improvement process, team care, optimizing patient self-management support, and outreach after the project ended. Practice facilitators worked with each practice, and its staff members, over a 12-month period, but did not work directly with patients.

### 2.4. Peer coaching and practice facilitation services

One intervention arm combined the two interventions. The recruited patients received PC services, and the practice worked with a practice facilitator, but the two interventions were not integrated.

### 2.5. Practice recruitment goal

The overall recruitment goal was to enroll and randomize 80 primary care practices – 50 in AL and 30 in NC – to one of the four interventions: 1) EUC, 20 practices; 2) EUC plus PC services, 20 practices; 3) EUC plus PF services, 20 practices; or 4) EUC plus both PC and PF services, 20 practices.

### 2.6. Geographic area

All practices located in AL or NC counties self-identifying as part of the Black Belt, or adjacent to the Black Belt region and seeing patients from that area, were eligible. In AL, the Black Belt included rural counties in the south-central part of the state spanning from the Mississippi border on the west to the Georgia border on the east. In NC, the Black Belt included rural counties in the eastern and central parts of the state.

### 2.7. Recruitment period

Practice recruitment took place in a rolling fashion over a 4-year period, from January 2016 to January 2020. Specifically, in year 1 of the study, the first aim was to engage rural primary care practices, patients with HTN, peer coaches, and community advisory boards in AL and NC to collaboratively finalize the PC and PF interventions. A second aim in the first year was to create the data systems for the trial. In years 2–5, the primary aim was to enroll 80 practices, along with 25 Black patients with persistently uncontrolled HTN from each practice, in the cluster-randomized trial to evaluate the three multi-component, multi-level functional interventions compared with EUC.

### 2.8. Inclusion criteria

Specific inclusion criteria for practices included: location in the Black Belt region of AL or NC or in the area immediately adjacent; serving a predominantly rural population; including a high proportion of indigent patients; including a high proportion of Black patients; internet access; EHR implementation; willingness to sign a letter of agreement to participate; willingness to provide space for patient evaluation and access to the EHR; willingness to identify a practice champion; willingness to modify structure and processes of care with the help of a practice facilitator; and willingness to work with peer coaches.

### 2.9. Practice engagement process

During the proposal development phase, study investigators secured letters of interest from more than 100 practices and practice organizations that were potentially eligible for inclusion in the study. These practices were invited to participate once the study was funded and the practice recruitment phase was initiated. Practices associated with AL and NC Practice-based Research Networks in the Black Belt were approached about participating, and study physicians made presentations at local meetings of the Medical Association of the State of AL and the local chapter of the American Academy of Family Physicians. In addition, the AL and NC Area Health Education Centers (AHEC), due to their familiarity with many of the targeted practices, assisted with the recruitment of practices.

The process of practice engagement (Fig. 1) began with an introductory letter and information sheet providing an overview of the study being sent by regular mail to the practice physician or practice manager. Within two weeks, a follow-up telephone call and/or email took place between a study investigator and the practice physician or practice manager. The telephone call/email was followed by additional calls and/or emails, as needed, and preferably an in-person visit. During these visits, study investigators, regional practice facilitators, and study data collectors met over lunch with the practice provider(s), practice manager, and other practice staff to describe the study in detail, including a description of what the responsibilities of the practice would be, as well as what benefits the practice and patients could expect to receive.

Once it was determined that a practice met the inclusion criteria and agreed to participate in the study, a signed letter of agreement to participate was obtained from the practice physician or other authorized official, and the practice champion was identified by the practice. The practice champion was the point person within each practice for communication about the project. Each practice designated a champion from among their staff, ideally a person with a stake in the success of the project and a willingness to advocate with their fellow practice staff to ensure the success of the project.

The study team also assisted the practice in obtaining a sponsor-required Federal Wide Assurance (FWA) number, if the practice did not already have one. If necessary, the study team worked with the relevant institutional review board to assure that practice staff participating in the research received the necessary training and certification in human subjects research. The practice then was placed in the queue for assessment of readiness to be randomized.

### 2.10. Practice readiness assessment

SEC investigators developed practice readiness criteria to assure that a minimum standard was met prior to moving a practice forward to randomization. Specifically, the readiness assessment of practices being considered for inclusion in the SEC was conducted in order to identify practices with the resources deemed necessary to participate in research, that were willing to implement and committed to organizational changes, and that were likely to complete study activities in a timely manner. Readiness assessment of practices prior to enrollment also was expected to contribute to retention of practices during the course of the study, help the study stay on budget, and limit timeline extensions. Practice readiness was assessed upon signing the letter of agreement (prior to enrollment) and again just prior to randomization to account for any changes that might have occurred in the interim.

Briefly, the practice readiness criteria included an assessment of: 1) expected practice financial stability over the study period and any plans to close the practice in the following three years for reasons such as retirement of the lead provider; 2) engagement and commitment of practice leadership to support changes required by the various interventions; and 3) major disruptions anticipated over the study period (e.g., key staff position becoming vacant, key staff member going out on family leave, new EHR being implemented, etc.). The quantitative

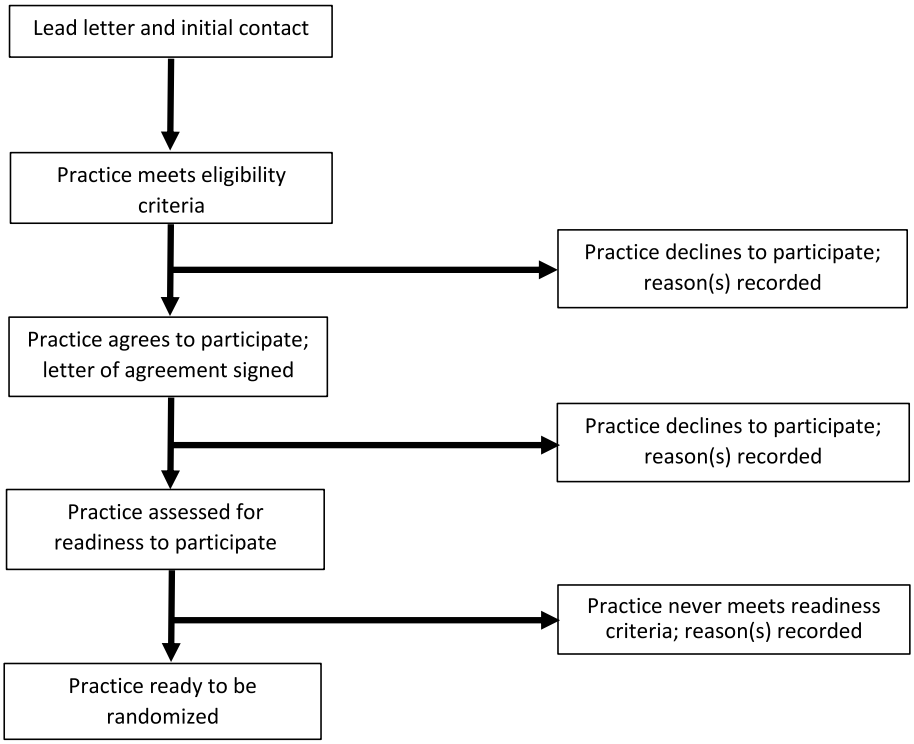



**Fig. 1.** Practice engagement scheme from initial contact through practice readiness for randomization for the Southeastern Collaboration to Improve Blood Pressure Control.

assessment included eight questions developed from the original Organizational Readiness for Implementing Change (ORIC) scale questions (Fig. 2). The scale includes two subscales: change commitment and change efficacy [5].

The survey was completed by providers (including physicians, physician assistants, nurse practitioners, and psychologists) and staff (including nurses, medical assistants, dietitians, health educators, health coaches, lab staff, social workers, management staff, and clerical staff) of each recruited practice. A Likert scale was used for responses: 1 (strongly disagree), 2 (disagree), 3 (neutral), 4 (agree), and 5 (strongly agree). An average score was generated from the responses for all personnel completing the survey at each practice, and this score, along with the level of agreement between scores of providers and staff, were used during assessment of practice readiness.

In addition to the results of the practice readiness assessment, other qualitative data were used in determining the readiness of a practice to be randomized. Practice characteristics, assessed by questionnaire, were considered, including practice type, years in operation, annual patient visits, practice busyness, the ability to search the EHR database by diagnosis and race, Patient-Centered Medical Home (PCMH) recognition by the National Committee for Quality Assurance (NCQA), number of full-time and part-time providers and staff, payer status, and patient demographics. A report generated by the workgroup member who interacted with the practice staff, feedback from the AHEC team, and any additional information available to the study team also were used in determining practice readiness.

Together, the quantitative readiness assessment score and qualitative data for each practice were presented during weekly meetings of the study Recruitment and Retention Committee to assess the readiness of each practice to be randomized. Specifically, these data were considered in making the decision on whether to move forward with randomization of the practice. The main driver in this decision was whether the practice was deemed able to complete the year-long intervention considering all available data, and whether there was agreement or strong agreement on at least four of the eight domains assessed by the practice readiness assessment. The multiple waves of randomization over four years permitted practices that were not ready for time-limited reasons, such as implementation of a new EHR, a staff member away on maternity leave, etc., to be considered for randomization at a later date.

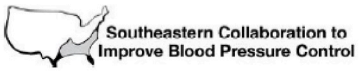
### 2.11. Randomization

The initial four practices – vanguard practices – were randomized to the four treatment arms of the trial, such that there was one practice in each of the four arms. The randomization assignment for the rest of the trial were drawn from the remaining pool of recruited practices meeting readiness criteria. The remaining practices were randomized over a four-year period using a block randomization approach, assuring balance across practice type (Federally Qualified Health Center [FQHC] vs. not) and also across states (AL vs. NC). The goal was to randomize 50 practices in AL and 30 in NC, reflecting the relatively larger relevant geographic region (Black Belt) in AL, along with the generally worse BP control noted in AL.

A mid-study protocol modification was approved by the sponsor and the study's Data and Safety Monitoring Board due to budgetary constraints. The modification of the study's design elevated the patient-level analysis to the primary analysis. This required less sample to achieve the study's main goals, resulting in 69 practices as the new practice recruitment goal.

### 2.12. Recruitment incentives/compensation

All randomized practices received the following as incentives and compensation for their participation: resources for hypertension management, including a laminated BP medication titration algorithm; a laptop computer with access to the Patient Activated Learning System (PALS) [14] patient education system; 25 home BP monitors to be distributed to the 25 participating patients in each practice; and $4000 in payments over 12 months following the attainment of various milestones: $500 upon enrollment of the practice (signed letter of agreement




**Practice Readiness Assessment**

Practice:_____ Date: _____

Respondent Name:_____Title: _____

The purpose of this assessment is to understand more about your practice's **readiness to makes changes in the way it provides care to patients.** All responses will be reported only as summary results. At first, only the Practice Champion should complete this assessment. Later, up to five (5) practice staff members will be asked to complete it, preferably representing each of the following roles: physician, other provider, clinical staff, non-clinical staff, and office management.

The overall goal of this study is to help practices improve blood pressure control in the "Black Belt" regions of Alabama and North Carolina using practice facilitators, peer coaches, and online education. In the questions below, "these changes" refer to the quality improvement activities we asked about on the About Your Practice questionnaire, specifically registries / population management / reports, following evidence-based protocols, and self-management support (online or peer coach). **Please share your perspective on your practice's readiness to implement these types of changes, thinking in terms of the way you provide care as a group.**

*( circle only one option )*

| | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|---|---|---|---|---|---|
| 1. We are committed to implementing these changes. | 1 | 2 | 3 | 4 | 5 |
| 2. We can keep track of progress in implementing these changes. | 1 | 2 | 3 | 4 | 5 |
| 3. We will do whatever it takes to implement these changes. | 1 | 2 | 3 | 4 | 5 |
| 4. We can support providers as they adjust to these changes. | 1 | 2 | 3 | 4 | 5 |
| 5. We can handle the challenges that might arise in implementing these changes. | 1 | 2 | 3 | 4 | 5 |
| 6. We can coordinate tasks so that implementation goes smoothly. | 1 | 2 | 3 | 4 | 5 |
| 7. We are motivated to implement these changes. | 1 | 2 | 3 | 4 | 5 |
| 8. Our practice is ready to implement these changes. | 1 | 2 | 3 | 4 | 5 |

9. What concerns do you have that might make it difficult to implement these changes?

_____

_____

_____

*Thank you for completing this assessment.*

**Fig. 2.** Practice readiness assessment instrument for the Southeastern Collaboration to Improve Blood Pressure Control.

to participate and randomization completed); $1500 when the 25 patients had been enrolled and baseline data collection completed; $1000 upon completion of the mid-point (6-month) follow-up assessment; and $1000 upon completion of final (12-month) data collection.

In addition, for all practices randomized to PC, enrolled patients were matched to a trained community peer coach who delivered a standardized telephone-based curriculum to each patient over 12 months. All practices randomized to PF received the assistance of a trained, certified practice facilitator for 12 months to assist the practice in implementing best practices and evidence-based guidelines for BP control, along with hands-on teaching on how to implement quality improvement in their practice.

At the patient level, all patients in each randomized practice were provided access to PALS, an online patient education system developed by physicians at Cornell University. PALS is a publicly available resource designed to provide health-related information specifically for patients with low health literacy and is independently reviewed for accuracy. All patients enrolled in each randomized practice received home BP monitors, along with $40 for each study visit, for a potential total of $120.

### *2.13. Recruitment and Retention Committee*

A Recruitment and Retention Committee was established to oversee practice recruitment and retention activities. Committee membership included the overall study principal investigator and staff from the parent institution (Weill Cornell Medicine); principal investigators, investigators, and staff (study managers, data collectors, data managers, statisticians, practice facilitators, and regional coordinators) from each site in AL (UAB) and NC (ECU and UNC); as well as the Project Officer from the National Heart, Lung, and Blood Institute. The Committee met weekly during the active practice recruitment period to review such topics as progress on recruitment goals, practice engagement and screening, readiness for randomization, and practice retention at each of the three study sites. Structured recruitment and retention reports, maintained in the study data management system (ClinvestiGator) [15], were reviewed in real time during each meeting.

## 3. Results

### *3.1. Timeline – initial contact to randomization of practices*

Contact was initiated with the first potentially eligible practice in

January 2016, and the final practice was randomized in January 2020. For the practices eventually randomized, the median (interquartile range [IQR]) time from first contact to enrollment (i.e., signing the letter of agreement to participate) was 30 (3–64) days, while the median (IQR) time from enrollment to randomization of the practice was 309 (46–528) days. Overall, the median (IQR) time from first contact to randomization was 360 (186–576) days for the 69 randomized practices. Delays between enrollment and randomization for some practices were due to the excessive time required to obtain an FWA number (for those that did not already have one) and the protracted time required to recruit and train an adequate number of peer coaches.

There were several instances of the recruitment process/practice randomization being placed "on hold" during the course of the trial. Some of these resulted from the practice readiness assessment process identifying such things as practice financial instability and staff shortages. Natural disasters, namely flooding and hurricanes, also caused a hold to be placed on the recruitment process at various times. In all cases, practice leadership agreed to the temporary holds, relationships were not negatively impacted, and the practices were randomized at a later date. Maintaining regular communication with the practices during the time that recruitment was on hold was an important factor in the eventual randomization of these practices.

### 3.2. Randomized practice characteristics

Contact was initiated with a total of 248 practices over the course of the study enrollment period (Fig. 3). Of these, 99 declined participation (66 immediate, active refusal, 24 passive refusal, and 9 withdrawing after signing the letter of agreement), 39 practices were ineligible, and 41 practices were being evaluated for inclusion when the target number of practices was reached. The remaining 69 practices expressed an interest in participating, were eligible for inclusion, and eventually were enrolled and randomized. This included 18 practices eventually randomized to EUC, 19 randomized to PC, 16 randomized to PF, and 16 randomized to PC plus PF (Table 1). Of the 69 practices randomized, 39 were through the UAB site, 20 through the ECU site, and 10 through the UNC site. Nearly half of practices (47.8%) were designated FQHCs, free clinics, or community health centers, with the remainder being private practices (36.2%), or part of a hospital system (15.9%). Randomized practices had been in operation for an average of approximately 19 years. Practices included on average more than 5 full- and part-time practitioners and nearly 14 full- and part-time staff. The randomized practices included a payer mix distributed fairly evenly among Medicare, Medicaid, health maintenance organization/preferred provider organization/commercial, and uninsured. Practices averaged nearly 12,000 patient visits per year and rated a mean 7.6 on a busyness scale of 1 (least busy) to 10 (most busy). On average, randomized practices self-assessed that just over 28% of their patients were 65 years of age or older, and more than half (56.7%) were Black. Approximately 30% of practices had received PCMH recognition by the NCQA. Nearly all practices had information systems that were searchable by diagnosis and race, while only 9 practices had a patient advisory board. There were no statistically significant differences in any of these practice characteristics over the four study conditions.

### 3.3. Recruitment challenges

Several challenges became apparent during the practice recruitment period. Especially in AL, many primary care practices in the Black Belt region have closed in the past several years, partially due to the exodus of practitioners as many rural hospitals have closed [16,17], significantly reducing the pool of potential practices in that state. Frequent staff and provider turnover in some practices contributed to practice instability, negatively impacting their practice readiness assessment. Some practices that were part of large healthcare networks proved to be challenging to enroll due to perceived Health Insurance Portability and Accountability Act of 1996 constraints and EHR access hurdles, as well as the additional layers of required approvals and the difficulty study personnel encountered when trying to interact with upper management/administration. Finally, many potentially eligible practices were located too far from the study centers, making it impractical to recruit them due to excessive travel time and associated costs that would be required.

### 3.4. Retention

Of the 69 primary practices that were enrolled in the study, only two (2.9%) were withdrawn over the duration of the study (Fig. 3), a much lower proportion of withdrawals than the projected 20% practice-level attrition. One EUC practice was withdrawn because of refusal to provide EHR access and because participant recruitment was exceedingly slow. One PC practice was withdrawn because it transitioned to a concierge clinic after randomization, making it ineligible to continue in the study.

### 3.5. Recruitment and retention facilitators

We employed several strategies that we believe facilitated practice

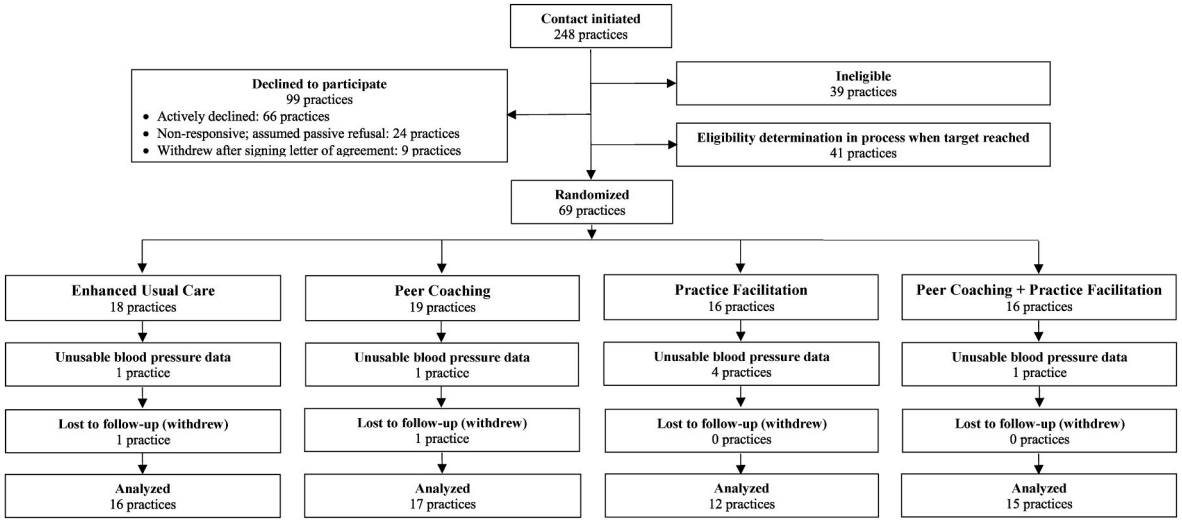



**Fig. 3.** Consort diagram for the Southeastern Collaboration to Improve Blood Pressure Control.

**Table 1**
Characteristics of practices randomized in the Southeastern Collaboration to Improve Blood Pressure Control.

| Characteristic | Trial arm | | | | | P value |
|---|---|---|---|---|---|---|
| | All | Enhanced usual care | Peer coaching | Practice facilitation | Peer coaching + practice facilitation | |
| **Number of practices** [n (%)] | 69 (100.0) | 18 (26.1) | 19 (27.5) | 16 (23.2) | 16 (23.2) | – |
| **Site** [n (%)] | | | | | | – |
| University of Alabama at Birmingham | 39 (56.5) | 10 (25.6) | 11 (28.2) | 9 (23.1) | 9 (23.1) | |
| East Carolina University | 20 (29.0) | 6 (30.0) | 5 (25.0) | 4 (20.0) | 5 (25.0) | |
| University of North Carolina at Chapel Hill | 10 (14.5) | 2 (20.0) | 3 (30.0) | 3 (30.0) | 2 (20.0) | |
| **Type of practice** [n (%)] | | | | | | 0.78 |
| Federally Qualified Health Center, free clinic, community health center | 33 (47.8) | 8 (44.4) | 9 (47.4) | 9 (56.3) | 7 (43.8) | |
| Private practice | 25 (36.2) | 6 (33.3) | 8 (42.1) | 6 (37.5) | 5 (31.3) | |
| Part of hospital system | 11 (15.9) | 4 (22.2) | 2 (10.5) | 1 (6.3) | 4 (25.0) | |
| **Years in operation** [mean ± SD] | 18.9 ± 15.0 | 23.3 ± 21.7 | 19.7 ± 11.6 | 18.4 ± 10.3 | 13.5 ± 12.7 | 0.30 |
| **Providers[a] and staff[b]** [mean ± SD] | | | | | | |
| Providers – full-time | 4.2 ± 7.6 | 6.6 ± 13.6 | 2.6 ± 2.1 | 3.1 ± 3.4 | 4.3 ± 4.9 | 0.42 |
| Providers – part-time | 1.4 ± 3.4 | 2.1 ± 4.1 | 1.4 ± 2.5 | 1.8 ± 4.5 | 0.1 ± 0.5 | 0.40 |
| Staff – full-time | 12.8 ± 17.1 | 19.7 ± 29.0 | 9.0 ± 6.9 | 12.1 ± 13.6 | 9.9 ± 5.9 | 0.23 |
| Staff – part-time | 1.1 ± 4.0 | 0.9 ± 1.7 | 0.8 ± 1.3 | 2.3 ± 7.7 | 0.4 ± 0.9 | 0.56 |
| **Payer mix** [%, mean ± SD] | | | | | | |
| Medicare | 23.2 ± 12.7 | 26.1 ± 9.4 | 22.5 ± 13.0 | 24.6 ± 13.4 | 19.5 ± 14.8 | 0.47 |
| Medicaid | 21.4 ± 13.0 | 19.8 ± 10.8 | 20.4 ± 15.5 | 22.8 ± 11.5 | 23.1 ± 14.3 | 0.85 |
| Dual Medicare/Medicaid | 9.1 ± 9.9 | 10.1 ± 10.3 | 9.2 ± 10.9 | 7.9 ± 8.2 | 9.1 ± 10.4 | 0.94 |
| Health maintenance organization, preferred provider organization, commercial | 23.7 ± 19.6 | 25.0 ± 17.8 | 26.9 ± 22.0 | 16.5 ± 13.9 | 25.6 ± 23.3 | 0.42 |
| Uninsured | 20.3 ± 21.1 | 15.6 ± 18.2 | 19.7 ± 19.0 | 26.9 ± 26.7 | 20.0 ± 20.6 | 0.49 |
| Other | 2.2 ± 5.6 | 3.4 ± 8.2 | 1.4 ± 4.0 | 1.3 ± 2.9 | 2.7 ± 5.8 | 0.62 |
| **Patient visits per year** [mean ± SD] | 11,890 ± 22,293 | 18,680 ± 36,960 | 8168 ± 6148 | 11,820 ± 23,928 | 9167 ± 8191 | 0.51 |
| **Practice busyness[c]** [mean ± SD] | 7.6 ± 1.5 | 7.8 ± 1.5 | 7.7 ± 1.2 | 7.2 ± 1.9 | 7.8 ± 1.3 | 0.57 |
| **Patients ≥ 65 years of age** [%, mean ± SD] | 28.6 ± 15.0 | 28.6 ± 15.0 | 29.4 ± 17.0 | 26.3 ± 13.3 | 29.8 ± 15.1 | 0.91 |
| **Patients who are Black** [%, mean ± SD] | 56.7 ± 22.0 | 55.8 ± 22.7 | 56.1 ± 24.3 | 59.4 ± 21.8 | 55.6 ± 20.3 | 0.96 |
| **Patient-Centered Medical Home recognition[d]** [n (%)] | 20 (29.9) | 5 (27.8) | 5 (27.8) | 6 (37.5) | 4 (26.7) | 0.90 |
| **Information system searchable by diagnosis** [n (%)] | 67 (98.5) | 17 (100.0) | 19 (100.0) | 15 (93.8) | 16 (100.0) | 0.35 |
| **Information system searchable by race** [n (%)] | 61 (92.4) | 16 (94.1) | 17 (94.4) | 14 (87.5) | 14 (93.3) | 0.86 |
| **Practice has a patient advisory board** [n (%)] | 9 (13.0) | 4 (22.2) | 1 (5.3) | 2 (12.5) | 2 (12.5) | 0.50 |

SD = standard deviation.
For characteristics "patient visits per year," "practice busyness," and "information system searchable by diagnosis," one practice had missing information.
For characteristic "Patient-Centered Medical Home recognition," two practices had missing information.
For characteristic "information system searchable by race," three practices had missing information.
[a] Providers are defined as physicians, physician assistants, nurse practitioners, and psychologists.
[b] Staff are defined as pharmacists, nurses, dietitians, medical assistants, laboratory technicians, health coaches, social workers, and management.
[c] Based on a scale of 0–10, where 10 is most busy.
[d] From the National Committee for Quality Assurance.

recruitment and retention during the course of this study. A practice readiness assessment was conducted, assuring that minimum standards were met related to financial stability of the practice, engagement and support of the study by practice leadership, and anticipated practice disruptions, prior to moving a practice forward to randomization. We ensured multiple interactions with the practice prior to randomization, including frequent telephone calls and emails to practice physicians and staff, along with in-person meetings at the practice to meet physicians and staff and present more comprehensively what the practice could expect from participating in the study. We required each practice to identify a practice champion, a highly regarded person within each practice who would advocate for the study among practice physicians and staff, and serve as the main conduit in the practice for study communications. Finally, we believe that incentives, including monetary, human resources (i.e., peer coaches), and material resources (i.e., laptop computer, BP monitors), were essential in facilitating practice recruitment and retention.

## 4. Discussion

Strategies for recruiting primary care practices in the SEC – a study comparing the effectiveness of two practical approaches to achieving better BP control – were described. A total of 248 practices were initially contacted about participating in the study, with 69 practices eventually randomized. A high percentage of randomized practices were retained throughout the study period. Several facilitators of recruiting and retaining practices (e.g., practice readiness assessment, multiple interactions with the practice, identification of a practice champion, and incentives), along with barriers to recruitment and retention (e.g., closing practices, practice staff turnover, and excessive distance of practices from the study center) were identified during the course of the study.

Of the 69 practices randomized, only two (approximately 3%) were withdrawn during the course of the study and thus were not included in the main analysis. Retention of 97% of randomized practices was much higher than the projected retention of 80% and much higher than the retention of practices seen in similar studies. For example, in a cluster-randomized effectiveness trial of a web-based diabetes intervention for physicians which randomized 205 rural primary care practices in 11 US Southeastern states, 39 practices (19.0%) did not provide follow-up data due to practices closing, withdrawing, or declining to send data [18].

The lower than anticipated number of practices withdrawing in the current study likely was at least partially due to the practice readiness assessment employed in this study. Practices were not randomized until study investigators, based on the results of the practice readiness assessment, were reasonably confident that the practices would be able to complete all required study activities within the specified time frame. In some cases, when the practice readiness assessment indicated that the

practice might not be ready, the practice was "put on hold" and reassessed at a later date and eventually randomized when the results of the subsequent practice readiness assessment indicated that conditions within the practice were more favorable for successful participation. Use of readiness assessment in practice-based research could be an important tool to prevent practice withdrawal, due to low commitment to participation or practice closures, in this important but expensive study design. Using a practice readiness assessment, a low-cost and quick option, gives practice-based clinical trial investigators the ability to better select from available practices in the sampling frame, stay on budget, limit timeline extensions, and improve both practice and patient retention.

Multiple interactions with a practice were required during the recruitment process, including those by telephone, email, and in-person meetings. Other studies also have demonstrated the importance of repeated interactions when recruiting primary care practices in trials. For example, an average of seven interactions per enrolled primary care practice was required in the Agency for Healthcare Research and Quality-funded initiative: EvidenceNOW: Advancing Heart Health in Primary Care [6]. We believe that having study investigators and staff meet in person with the practice physician and all relevant staff at the practice during the practice recruitment process was an especially effective aid in the recruitment and retention of practices. In short, showing up at practices, and not relying solely on electronic means of connecting with practices, works. In an analysis of the yield of strategies used to recruit primary care practices to a randomized trial to improve cardiovascular disease risk factor management, recruitment approaches based on in-person meetings yielded the most recruited practices per effort [19]. In-practice presentations, while expensive and time consuming, were found to be a valuable adjunct for the recruitment of general practices in the Integrated Solutions for Sustainable Fall Prevention (iSOLVE) cluster randomized controlled trial in Australia [7]. Involving all practice staff in initial practice visits was shown to be important in retaining practices in a multicenter randomized controlled trial of an intervention to optimize secondary prevention for coronary heart disease in primary care [20].

However, traveling to practices is expensive when factoring in investigator and staff time, car rental, fuel prices, etc. This was especially true in the current study which included rural practices that were somewhat isolated. Multiple trips were required for each practice, many of which were at least 2 h each way. The costs associated with these practice visits was one of the primary reasons why the number of practices had to be reduced from 80 to 69. Funding agencies should acknowledge these costs and allow appropriate budgeting for future trials. Pragmatic trials are not necessarily "cheap and easy" as some might believe, especially trials conducted in rural areas, which are in greatest need of the products of such trials.

The overall practice busyness score of 7.6 (with 10 being most busy) showed how busy on average practices included in the study were. The effect of this on recruitment should not be underestimated, and the primary responsibility of practice providers and staff to serve their patients should be considered when recruiting a practice for a trial. It is critical to work around the practice's schedule during the screening and randomization process. For example, we planned recruitment meetings with practice personnel during their midday break and provided them with lunch. To ensure retention, it is equally important to ensure that all components of the study protocol, including the delivery of interventions and data collection activities, are conducted in such a way as to result in the least disruption of normal practice activities as possible, respecting both practice staff time and space. For example, several practices offered SEC study staff a dedicated place to access the practices EHRs, in order to not disturb practice staff performing their regular duties. In NC, a quarter of the sites enrolled allowed the study team to access EHRs remotely, eliminating the need to occupy space or tie up a computer in the clinic.

Previous studies have noted some of the same facilitators of practice recruitment as we identified. For example, a practice champion was found to be a significant deciding factor in a practice proceeding to randomization in the iSOLVE trial [7]. Incentives offered to the practices – including cash payments – were important aids to recruitment and retention of practices in the current study. In agreement with this finding, payments upon meeting pre-agreed targets was shown to be an important factor in retaining general practices in clinical trials in a case study conducted in the United Kingdom [8]. Other studies recruiting primary care practices also have identified similar recruitment challenges to ours. For example, the TRANSLATE CKD study, which approached 114 primary care practices for a group randomized study, reported the burden on recruitment imposed by the multiple layers of approval required by some practices [21].

This study had several strengths, including dedicated staff with the training to interact with practices using a variety of modalities (including face-to-face visits), the use of a robust practice readiness assessment, and the establishment of a committee focused on recruitment and retention of practices. It should be noted that nearly half of the practices randomized were FQHCs, free clinics, or community health centers, which could somewhat limit the generalizability of the findings.

## 5. Conclusions

Overall, our findings underscore the importance of a systematic, structured, and comprehensive approach to recruiting primary care practices in a pragmatic implementation trial. Specifically, we have demonstrated the importance of including several practice recruitment strategies, including practice readiness assessment, frequent interactions, practice champions, and incentives, to ensure that recruitment goals are met. These approaches should receive due consideration when planning future trials targeting primary care practices.

## Ethics approvals

The UAB Institutional Review Board for Human Use approved the study protocol on July 6, 2015 (number: IRB-150702001). The UNC Office of Human Research Ethics approved the study protocol on January 25, 2016 (number: 15–2687). The ECU University & Medical Center Institutional Review Board approved the study protocol on February 15, 2016 (number: UMCIRB 16–000040). The Weill Cornell Medicine Institutional Review Board approved the study protocol on June 9, 2016 (number: 1603017096). This trial was registered at ClinicalTrials.gov (NCT02866669).

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## Author contributions

**James M. Shikany:** Conceptualization, Methodology, Data curation, Formal analysis, Writing – original draft **Monika M. Safford:** Methodology, Writing – original draft, Project administration, Funding acquisition **Andrea L. Cherrington:** Methodology, Writing – review & editing, Project administration **Jacqueline R. Halladay:** Methodology, Writing – review & editing, Project administration **Muna Anabtawi:** Methodology, Data curation, Writing – review & editing, Project administration **Erica L. Richman:** Methodology, Data curation, Writing – review & editing, Project administration **Alyssa D. Adams:** Methodology, Data curation, Writing – review & editing, Project administration **Charlotte Holt:** Conceptualization, Writing – review & editing **Suzanne**

**Oparil:** Data curation, Writing – review & editing **Orysya Soroka:** Formal analysis, Writing – review & editing **Doyle M. Cummings:** Conceptualization, Methodology, Writing – review & editing, Project administration. All authors have read and approved the final manuscript.

## Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Monika M. Safford: Founder and owner of MedExplain, Inc., a patient education company.

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