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Implementation of Multifaceted Patient-Centered Treatment Strategies for Intensive Blood Pressure Control (IMPACTS): Rationale and design of a cluster-randomized trial[☆]

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Background The Systolic Blood Pressure Intervention Trial (SPRINT) reported that intensive blood pressure (BP) treatment reduced cardiovascular disease and mortality compared to standard BP treatment in hypertension patients. The next important question is how to implement more intensive BP treatment in real-world clinical practice. We designed an effectiveness-implementation hybrid trial to simultaneously test the effectiveness of a multifaceted intervention for intensive BP treatment and its feasibility, fidelity, and sustainability in underserved hypertension patients.

Methods Implementation of Multifaceted Patient-Centered Treatment Strategies for Intensive Blood Pressure Control (IMPACTS) is a cluster randomized trial conducted in 36 Federally Qualified Health Center clinics in Louisiana and Mississippi. Federally Qualified Health Center clinics were randomized to either a multifaceted intervention for intensive BP treatment, including protocol-based treatment using the SPRINT intensive BP management algorithm, dissemination of SPRINT findings, BP audit and feedback, home BP monitoring, and health coaching, or enhanced usual care. Difference in mean systolic BP change from baseline to 18 months is the primary clinical effectiveness outcome, and intervention fidelity, measured by treatment intensification and medication adherence, is the primary implementation outcome. The planned sample size of 1,260 participants (36 clinics with 35 participants each) has 90% power to detect a 5.0-mm Hg difference in systolic BP at a .05 significance level and 80% follow-up rate.

Conclusions IMPACTS will generate critical data on the effectiveness and implementation of a multifaceted intervention for intensive BP treatment in real-world clinical practice and could directly impact the BP-related disease burden in minority and low-income populations in the United States. (*Am Heart J* 2020;230:13-24.)

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Cardiovascular disease (CVD) is the leading cause of death in the United States, and hypertension is a major modifiable risk factor for CVD.¹ According to the 2017 American College of Cardiology (ACC)/American Heart Association (AHA) blood pressure guideline, 45.4% of US adults, or 105 million individuals, had hypertension in 2015-2016, and only 43.5% of those treated had their blood pressure (BP) controlled.^{2,3} Hypertension control rates are also much lower among populations with health disparities.^{2,4} Hypertension and related CVD disproportionately affect people in the Southeastern United States. Mississippi and Louisiana residents are ranked first and fifth highest in CVD mortality and fourth and fifth highest in hypertension prevalence, respectively, out of the 50

states and the District of Columbia.^{5,6} The risk of hypertension is also higher among African Americans compared to whites within Louisiana and Mississippi.^{7,8}

The Systolic Blood Pressure Intervention Trial (SPRINT) was a multicenter, randomized, controlled trial which compared the effects of intensive antihypertensive treatment (achieved mean systolic BP 121.5 mm Hg) versus standard treatment (achieved mean systolic BP 134.6 mm Hg) on CVD and mortality among 9,361 persons aged ≥ 50 years with a systolic BP of ≥ 130 mm Hg and an increased risk of CVD.⁹ The trial was stopped early after a median follow-up of 3.26 years because intensive BP treatment significantly reduced CVD by about 25% and all-cause mortality by about 27% compared to standard BP treatment.⁹ In addition, we conducted a network meta-analysis of 42 clinical trials with 144,220 patients and found dose-response associations between mean achieved systolic BP and risk of CVD and mortality, with the lowest risk at 120-124 mm Hg.¹⁰ These findings further support more intensive BP control among patients with hypertension.

Although the efficacy of antihypertensive treatment has been demonstrated in clinical trials,^{10,11} this benefit has not been maximized in the United States, particularly in populations with health disparities.¹² Traditionally, minorities and low-income populations are underrepresented in clinical trials and benefit less from clinical research.¹³ This may contribute to health disparities in the United States. An important challenge for hypertension control in populations with health disparities is the lack of effective, adoptable, and sustainable implementation strategies to improve providers' adherence to clinical guidelines and patients' adherence to antihypertensive treatment.¹²

Most recent clinical practice guidelines recommend lower BP treatment targets than in the past, but the specific BP goal varies.^{3,14-17} The 2017 American College of Cardiology/American Heart Association (ACC/AHA) BP guideline recommends initiating drug treatment for those with an average BP of $\geq 130/80$ mm Hg who are at high risk for CVD (preexisting CVD or an estimated 10-year risk atherosclerotic CVD [ASCVD] of $\geq 10\%$).³ For adults without preexisting CVD and an estimated 10-year ASCVD risk $< 10\%$, the BP threshold for drug treatment is $\geq 140/90$ mm Hg.³ After initiation of antihypertensive drug therapy, regardless of ASCVD risk, the recommended BP target is less than 130/80 mm Hg.³

Barriers to BP control have been reported at the system, provider, patient, and community levels.^{12,18-22} Table I shows barriers reported in the literature; those identified during focus group discussions we conducted with Federally Qualified Health Center (FQHC) administrators, providers, and patients; and proposed strategies to overcome these barriers. Several strategies are proven to be effective for improving hypertension control. Team-based collaborative care, consisting of either nurses or

pharmacists working with primary care providers and patients, improved BP control in hypertensive patients.^{23,24} Interactive physician education has also resulted in improvements in professional practice and BP control.²⁵ Stepped-care protocol-based treatment, including use of treatment protocols and algorithms, has been successfully applied to hypertension control.^{26,27} Home BP monitoring has been recognized as an effective tool in hypertension management.^{24,28} Several approaches to improve adherence to antihypertensive medications, including motivational health coaching, have been proven effective.^{29,30} BP audit and feedback to providers was effective for BP control.³¹ Patient and care provider engagement is the key to a successful intervention program.^{3,32} Shared decision-making interventions have shown positive effects on patients' participation, satisfaction with their treatment, knowledge about the disease, adherence, and clinical outcomes.³³ We have recently conducted a meta-analysis of 100 randomized trials to study the effect of implementation strategies on BP control.²⁴ This study found that multilevel, multicomponent strategies, followed by patient-level strategies, are most effective for BP control in patients with hypertension and should be used to improve hypertension control.²⁴

Methods

Objectives and specific aims

The overall objective of the Implementation of Multifaceted Patient-Centered Treatment Strategies for Intensive Blood Pressure Control (IMPACTS) study is to test the effectiveness, implementation, and sustainability of multifaceted strategies to implement a stepped-care protocol adapted from the SPRINT intensive-treatment algorithm on BP control in FQHC clinics. FQHCs receive federal funding under Section 330 of the Public Health Service Act to provide health care for underserved communities.³⁴ Aiming for more rapid translation to clinical practice, the IMPACTS study uses an effectiveness-implementation hybrid type 2 design.³⁵ The dual focus on effectiveness and implementation will help ensure that the intervention can be feasibly adopted outside of the study into real-world primary care settings.

The IMPACTS study has the following 3 specific aims: (1) to test the effectiveness of a multifaceted intervention program to implement a stepped-care protocol for intensive BP treatment (systolic BP < 120 mm Hg) on BP and quality of life compared to enhanced usual care; (2) to assess the acceptability, adoption, feasibility, and fidelity of a multifaceted implementation strategy for intensive BP treatment in patients, provider teams, and FQHCs; and (3) to evaluate the sustainability of a multifaceted implementation strategy for intensive BP treatment among patients, provider teams, and FQHC clinics in a posttrial follow-up study.

Table I. Barriers to hypertension control and strategies to overcome them

Barriers reported in the literature	Barriers identified by focus group discussion	Proposed strategies to overcome barriers
<p>Systems level (inner setting)</p> <p>Poor access to primary care</p> <p>Lack of continuity of care</p> <p>Lack of reimbursement for health counseling</p> <p>Costs of medications</p> <p>Absence of clinical decision support systems</p>	<p>Lack of continuity of care</p> <p>Lack of consistency in BP treatment</p> <p>Provider burnout</p> <p>Language/cultural barriers for health education</p> <p>No reimbursement for health coaching</p> <p>Costs of medications</p> <p>Lack of standardization for BP measurement</p>	<p>Dissemination of updated guidelines to administrators</p> <p>Stepped-care treatment protocol</p> <p>Team-based collaborative care</p> <p>Assignment of some responsibilities for health coaching to pharmacists/nurses</p> <p>BP audit and feedback</p> <p>Standardization of BP measurement</p>
<p>Provider level (individual/team characteristics)</p> <p>Nonadherence to treatment guidelines</p> <p>Uncertainty that office BP represents usual BP</p> <p>Failure to titrate antihypertensive regimen</p> <p>Insufficient time for health coaching</p>	<p>Safety/acceptability concerns about treating to lower target</p> <p>Inaccurate BP measurements</p> <p>Uncertainty that office BP represents usual BP</p> <p>Uncertainty that patients are taking medications as prescribed</p> <p>Insufficient time for health coaching</p>	<p>Dissemination of updated guidelines to providers</p> <p>Team-based collaborative care</p> <p>Stepped-care treatment protocol</p> <p>BP measurement training</p> <p>Home BP monitoring</p> <p>BP audit and feedback</p> <p>Assignment of some responsibilities for health coaching to pharmacists/nurses</p>
<p>Patient level (individual characteristics)</p> <p>Poor adherence to medications</p> <p>Lack of hypertension knowledge</p> <p>Health beliefs/risk perception</p> <p>Low health literacy</p> <p>Poor motivation</p> <p>Medication costs</p> <p>Medication side effects</p>	<p>Low health literacy</p> <p>Forgetfulness around taking medications</p> <p>Confusion about purpose of medications</p> <p>Resistance to lifestyle changes</p> <p>Medication costs and availability</p> <p>Reluctance to seek health care</p> <p>Discomfort asking questions to providers</p> <p>Use of herbs instead of BP medications</p> <p>Cost of home BP monitors</p> <p>Lack of transportation to clinic and pharmacy</p> <p>Socioeconomic limitations and stress</p>	<p>Dissemination of updated guidelines to patients in a manner that reflects health literacy and culture</p> <p>Home BP monitoring</p> <p>Health coaching that addresses</p> <ul style="list-style-type: none"> • Medication adherence, eg, pill box, reminders • Lifestyle modification • Low-cost drugs plan • Referrals to social workers <p>Discussion of medication adverse effects with providers</p>

Study setting and participants

FQHCs are community-based health centers that receive federal funding to provide comprehensive primary care in underserved areas regardless of insurance coverage or ability to pay. All 42 FQHCs in south Louisiana and Mississippi within 4 hours of New Orleans were evaluated as potential partners for the study. Because of staffing logistics, FQHCs outside of the greater New Orleans area were eligible to participate if they had at least 4 clinics meeting predefined clinic eligibility criteria (Table II). New Orleans FQHCs were eligible to participate with any eligible clinics. Of the 42 FQHCs in the region, 8 are participating in the study, 8 were not interested in participating, and 26 did not have enough eligible clinics to participate. A total of 36 clinics from the 8 participating FQHCs in Louisiana and Mississippi were eligible and are participating in the IMPACTS trial. Of them, 18 clinics were randomly assigned to the multifaceted intervention and 18 clinics to enhanced usual care, stratified by FQHC (Figure 1). FQHCs received supplements to cover operational costs for all participating clinics and reimbursement for health coaching and provider visits for intervention clinics only.

To increase the generalizability of our study findings to real-world primary care settings, minimal patient-level eligibility criteria are used (Table II). Briefly, patients aged 40 years or older with elevated BP (systolic ≥ 130 mm Hg if taking antihypertensive medication or ≥ 140 mm Hg if not medicated) are recruited from each participating FQHC clinic. Using electronic health record systems at each FQHC, potentially eligible patients with elevated BP seen in clinic during the previous year are identified. A waiver of HIPAA authorization is approved to obtain patient contact information for recruitment purposes. Patients identified as potentially eligible for the study are contacted via an introductory letter from the research team with both Tulane University and their FQHC logos and a subsequent phone call to assess their willingness to participate and preliminary eligibility. After prescreening, potentially eligible participants are scheduled for a screening visit in the clinic with study staff. Patients are also recruited from provider referrals and in-clinic recruitment.

Multifaceted intervention program

The multifaceted intervention program is delivered over 18 months and includes protocol-based treatment

Table II. Eligibility criteria for FQHC clinics and study participants

Eligibility criteria for FQHC clinics

- Affiliated with participating FQHCs and not sharing providers or nurses/pharmacists with other participating clinics.
 - Predominantly managing underserved populations with health disparities (ethnic minorities, low-income groups, and residents of rural areas and inner cities).
 - Having electronic medical record systems.
 - Serving >200 hypertension patients (ICD-10-CM I10-I15) during the previous year.
 - Not participating in other hypertension control programs.

Eligibility criteria for study participants

- Men or women aged ≥ 40 y who receive primary care from the participating FQHC clinics.
 - Systolic BP ≥ 140 mm Hg at 2 screening visits for those not taking antihypertensive medication or systolic BP ≥ 130 mm Hg at 2 screening visits for those taking antihypertensive medications.
 - Pregnant women, women planning to become pregnant in the next 18 m, or women of childbearing potential and not practicing birth control will be excluded.
- Patients with *end-stage renal disease*, defined as dialysis or transplantation, will be excluded.
- Able to understand English
 - No plans to change to a primary health care provider outside of the FQHC clinic during the next 18 m
 - Individuals unlikely to complete the study, such as those who plan to move out the study area during the next 18 m, temporary migrant workers, homeless persons, and those whose BP cannot be accurately measured due to an arm circumference ≥ 50 cm will be excluded.
 - No immediate family members are staff at their FQHC clinic.*
 - Persons who cannot give informed consent will be excluded.

*To avoid self-selection of intervention group.

using the SPRINT stepped-care intensive BP management algorithm; dissemination of SPRINT study findings among provider teams, patients, and administrators; team-based collaborative care; BP audit and feedback; home BP monitoring; and health coaching on antihypertensive medication adherence and lifestyle modification.

Conceptual framework. The Consolidated Framework for Implementation Research was used to guide the development of the intervention and evaluation plans in the IMPACTS study based on its flexibility and comprehensive implementation constructs across socioecological levels.^{36,37} The framework consists of 7 domains that describe the internal and external contexts of implementation that affect the likelihood of a clinical guideline or medical innovation being translated into routine care: intervention characteristics, outer setting, inner setting, characteristics of individuals and teams, process of implementation, implementation outcomes, and clinical outcomes. Features of these 7 domains relevant to the IMPACTS study are summarized in [Figure 2](#).

Core intervention. The core intervention is a stepped-care protocol adapted from the SPRINT intensive-treatment algorithm ([Figure 3](#)). Primary care providers, nurses/pharmacists, and patients work collaboratively to establish an individualized treatment plan and BP goal for each patient. Findings from the SPRINT trial, other clinical trials, and meta-analyses clearly support a lower BP target for further reductions in CVD and all-cause mortality.^{9-11,38} The 2017 ACC/AHA hypertension guideline recommended a BP treatment target of <130/80 mm Hg based on clinical BP measurements,³ which might be, on average, 10 mm Hg higher than BP measurements in research settings.¹⁴ The objective of our study is to implement the SPRINT intensive BP intervention in

populations with increased CVD risk and health disparities. Therefore, we recommend a systolic BP target of <120 mm Hg for all patients 40 years and older with hypertension. Furthermore, a diastolic BP target of <80 mm Hg was used based on the 2017 ACC/AHA guidelines. However, BP treatment targets can be individualized based on each patient's needs in this implementation study.

All antihypertensive regimens should include 1 or more drug classes proven to reduce CVD risk, that is, a thiazide or thiazide-like diuretic, calcium channel blocker, angiotensin-converting enzyme inhibitor, or angiotensin receptor blocker.³⁹⁻⁴² Angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, and calcium channel blocker combine effectively with diuretics for lowering BP and CVD risk.⁴³ Other classes may also be added for BP control. Prescribing of antihypertensive medications and management of side effects are addressed by health care provider teams.

Intervention clinic participants visit their FQHC clinic monthly for the first 3 months after their baseline clinic visit for BP checks and medication adjustments as needed. After the first 3 months, clinic visits are scheduled every 3 months for the duration of the trial if BP is below target. If BP is above target at 3 months, monthly visits continue until the target is achieved. Following this, visits are scheduled every 3 months. Milepost visits are conducted every 6 months throughout follow-up. If the target systolic BP is not achieved at a milepost visit, then an antihypertensive drug from a class different from what is being taken should be added, unless there are contraindications.

Implementation strategies. The IMPACTS study uses a combination of proven-effective strategies to

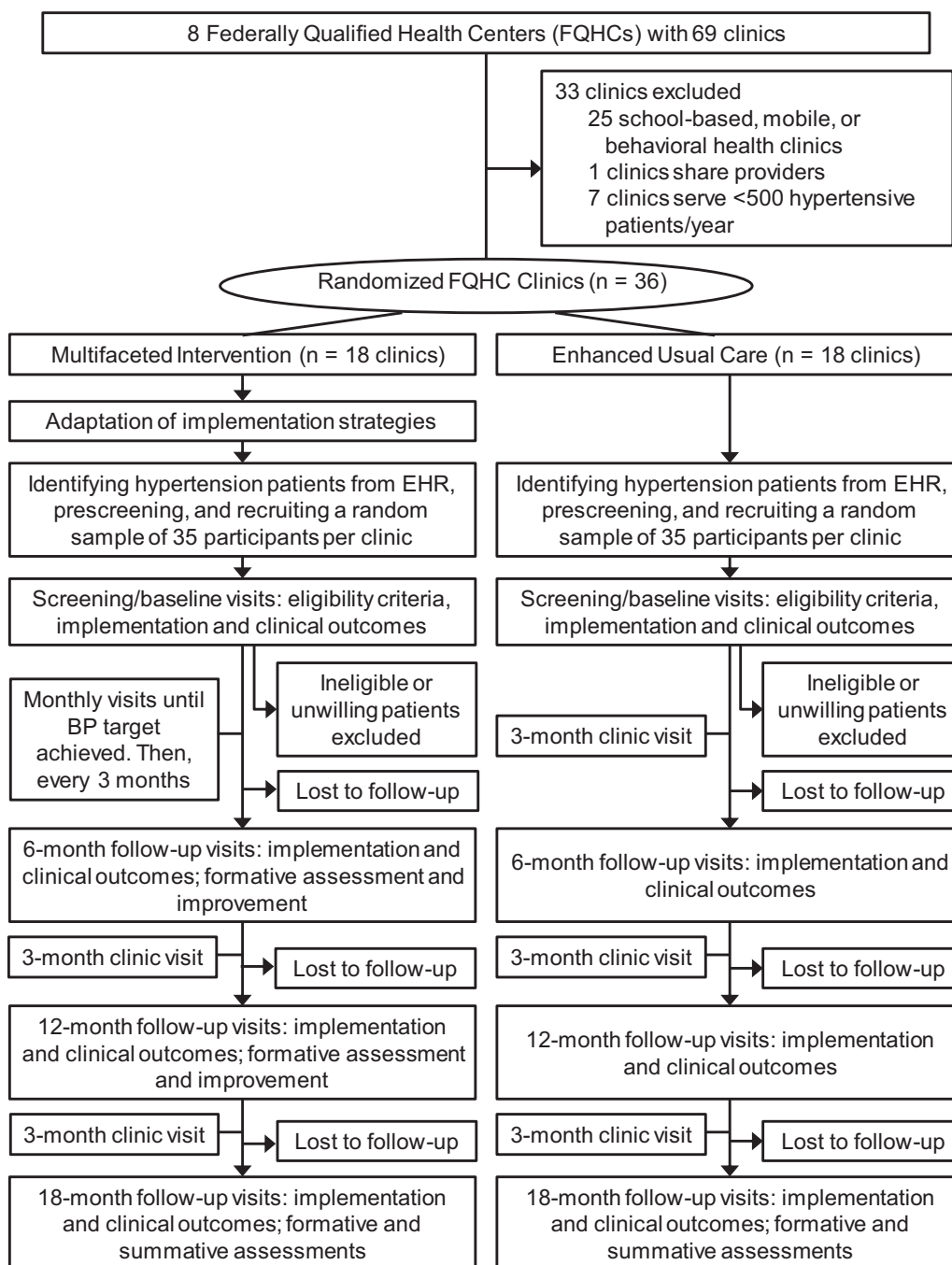
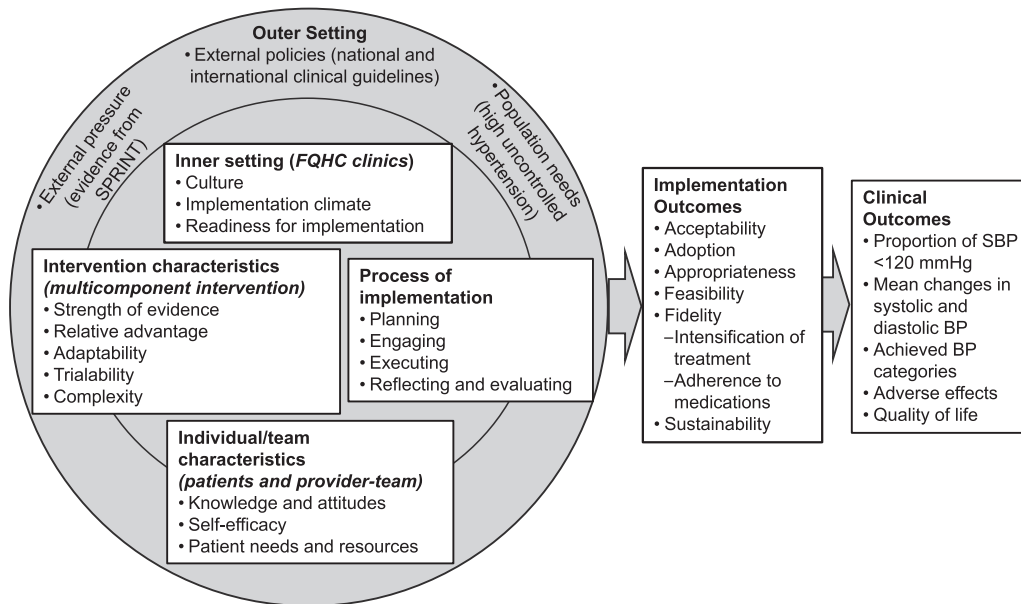


Figure 1

Study design of the IMPACTS trial.

implement the core intervention. In preparation for implementation, we have assessed each FQHC's readiness for implementing the multifaceted intervention using the organizational readiness for implementing change scale.⁴⁴ Findings from organizational readiness for implementing change and initial conversations with

clinic administrators and staff were used to identify barriers to intervention adoption and tailor implementation strategies. All providers were trained to follow ACC/AHA hypertension clinical guideline for BP management. In addition, providers in the intervention clinics received additional interactive training on the SPRINT intensive BP

Figure 2

IMPACTS conceptual framework: 4 interrelated internal domains (intervention characteristics, individual/team characteristics, inner setting, and process of implementation) are surrounded by the outer setting, indicating interactions among these domains. An arrow to the right of these domains points to implementation outcomes, which influence clinical outcomes.

intervention protocol. Any concerns about the intensive BP target were addressed during the training.

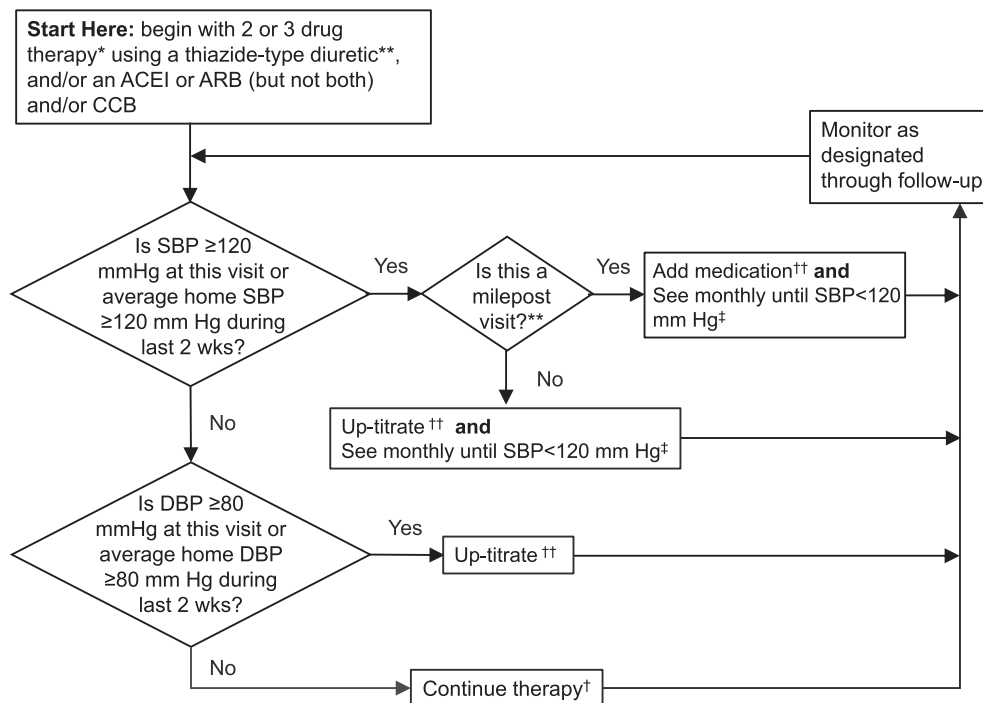
Implementation strategies include dissemination of the SPRINT study findings, team-based collaborative care, BP audit and feedback, home BP monitoring, and health coaching. We disseminate the SPRINT study findings to provider teams, patients, and administrators in the intervention clinics using interactive in-person and online workshops and printed training materials. Training (initial and ongoing) includes SPRINT study findings and the intensive BP management strategy using SPRINT treatment protocols including medication selection and algorithms. Providers and staff were also trained in proper BP measurement technique. To encourage stepped-care treatment, providers received a laminated pocket card containing the treatment algorithm; in addition, the provider visit form includes recommended treatment information. Further, IMPACTS participants have been flagged in the electronic health record systems at each FQHC to remind staff to follow the intervention with those patients. In clinics with busy schedules, standing spaces are reserved on provider schedules for IMPACTS patients so that they can be seen according to the intervention schedule. All provider and health coaching visits were scheduled by FQHC clinic staff.

We have worked with each FQHC to develop a feasible and sustainable collaborative care team. Based on availability of in-house nurses and pharmacists, we use a

nurse-provider or pharmacist-provider combination. Providers conduct a clinical evaluation of patients, prescribe initial antihypertensive medications based on a treatment protocol, prescribe medication changes based on patients' responses, and supervise nurses/pharmacists. Nurses/pharmacists function as case managers to coordinate patient care and regularly and systematically review patients' clinic and home BP. In circumstances where a nurse or pharmacist is not available, study staff have assumed the backup role of health coaching. Teams are encouraged to regularly meet and stay in constant communication regarding patient care. Health coaches or in-house quality improvement staff provide audit and feedback to providers by tracking patients' BP readings over time and informing providers of those whose BP is not at target. In addition, study staff provide a list of patients whose BP was not controlled at study visits to each FQHC regularly. Mean BP of IMPACTS participants for each provider in their FQHC is also provided for comparison.

Nurses, pharmacists, or clinic medical assistants provide health coaching to patients including discussion of the SPRINT findings and intensive BP treatment with patients. They emphasize lifestyle modification and medication adherence and suggest strategies for overcoming treatment adverse effects and poor adherence during patients' clinic visits or by phone. Each intervention clinic patient receives a home BP monitor and

Figure 3



Stepped-care treatment algorithm adapted from the SPRINT trial.*Participants ≥ 75 years old with systolic BP < 140 mm Hg on 0-1 medication at study entry may begin with a single agent. A second medication should be added at the 1-month visit if participant is asymptomatic and systolic BP ≥ 130 mm Hg.**Participants with advanced chronic kidney disease may use loop diuretic.†Use clinical judgment to adjust therapy due to side effects.††Consider consulting with hypertension specialist before adding a fifth antihypertensive medication.‡Rarely, clinical decision may be made to suspend or discontinue intensification of therapy.

instruction on its use from the health coach. Patients are instructed to take at least 6 BP measurements per week (1 in the morning and 1 in the evening on each of 3 days). At each health coaching visit, health coaches measure each participant's clinic BP and average home BP values over the previous 2 weeks. This information is recorded on a form that is given to the provider for the patient's appointment along with the treatment algorithm. The provider records any treatment changes or reasons for not adjusting treatment on the form. The health coach then follows up with the patient as needed after the provider visit.

Implementation strategies have been adapted based on patient characteristics and clinic personnel and practices for each participating FQHC during the adaptation phase. These include adapting the make-up of teams for intervention delivery and dividing up other responsibilities for care coordination and health coaching depending on what clinic staff is available. Furthermore, in most clinics, patients keep track of their home BP monitoring values in a paper log and bring it to their health coaching appointments, but in some clinics with telemonitoring

capacity, we have purchased monitors that allow for electronic transmission of BP values. During the COVID-19 state-at-home orders, we have further adapted intervention delivery to allow for telehealth visits with providers and health coaching by phone and video.

Enhanced usual care. In clinics randomized to enhanced usual care, we conduct a brief webinar education session on the 2017 ACC/AHA hypertension guideline and findings from the SPRINT trial. In addition, we train providers and staff on proper BP measurement technique. Otherwise, there is no active intervention, and all enhanced usual care clinics follow their routine clinic practice for the management of hypertensive patients. Contamination between multifaceted intervention and enhanced usual care was avoided or reduced by only including clinics that did not share providers with other clinics within the FQHC and by additional training of providers when providers do move to a new study clinic.

Clinical effectiveness and implementation outcomes

The primary clinical outcome is the difference in mean change of systolic BP from baseline to 18 months

Table III. Clinical effectiveness and implementation outcomes

Clinical effectiveness outcomes

Primary clinical outcome

- The difference in mean change of systolic BP from baseline to 18 m between intervention and enhanced usual care groups.

Secondary clinical outcomes (comparing intervention and enhanced usual care groups)

- The difference in the proportion of patients with systolic BP <120 mm Hg at 18 m
- The difference in the proportion of patients with systolic BP <130 mm Hg at 18 m
- The difference in the proportion of patients with a >30-mm Hg reduction in systolic BP from baseline to 18 m
- The difference in mean change of diastolic BP from baseline to 18 m
- Mean change of health-related quality of life scores from baseline to 18 m

Implementation outcomes

Fidelity (primary implementation outcome)

- At the participant level, adherence to medication and numbers and proportions of health coaching sessions attended, home BP readings taken, and provider visits completed compared to the expected number
- At the provider level, numbers and proportions of visits at which medication was initiated or titrated according to treatment protocol and numbers and proportions of medication intensifications every 6 m compared to control group providers
- At the health coach level, numbers and proportions of health coaching sessions conducted compared to the expected number

Adoption

- The proportion of intervention clinics adopting the BP treatment goal and protocol

The proportion of intervention clinics adopting the multifaceted strategy

- The proportion of providers and health coaches completing training sessions

Appropriateness

- Perceived relevance and usefulness of the intervention in administrators, patients, and providers

Feasibility

- The utility of the multifaceted strategy in intervention clinics

Acceptability

- Satisfaction with the multifaceted strategy in patients, providers, and health coaches

Sustainability

- The extent to which the multifaceted strategy is maintained at intervention clinics after the study
- The proportion of trained providers continuing protocol-based treatment after the study
- The proportion of trained staff continuing health coaching after the study
- The proportion of enrolled patients continuing home BP monitoring and BP control after the study

between the intervention and enhanced usual care groups (Table III). Blood pressure at baseline and at 18 months is measured 3 times at each of 2 clinic visits by certified research staff at both intervention and usual care clinics. The average of the 6 measurements is used as the average BP. Secondary clinical outcomes include differences between intervention and enhanced usual care groups at 18 months in the proportion of patients with systolic BP <120 mm Hg, the proportion of patients with systolic BP <130 mm Hg, the proportion of patients with a >30-mm Hg reduction in systolic BP, mean change of diastolic BP, and mean change in health-related quality of life.

The primary implementation outcome is the fidelity of the intervention, that is, intensification of treatment (titration or addition of new medications) and adherence to medications (Table III). Other implementation outcomes include acceptability, adoption, appropriateness, feasibility, and sustainability.

Data collection

Data collection of clinical and implementation outcomes is conducted at baseline and at 6, 12, and 18 months of follow-up by trained, certified research staff based at both intervention and enhanced usual care clinics (Table IV). Two data collection visits between 1

and 28 days apart occur at baseline and at 18 months to obtain repeat BP measurements. In addition, a posttrial follow-up visit is conducted 12 months after the end of the National Institutes of Health–sponsored intervention to examine the sustainability of the intervention program. At the posttrial visit, we collect data on implementation and clinical outcomes from patients, provider teams, and administrators from each FQHC clinic. To ensure participant retention, study visits are coordinated with patients' regular clinic visits to reduce time burden, reminder calls are made prior to participants' clinic visits, modest incentives and small gifts are given to participants, and study staff with excellent interpersonal skills are used for the study.

A questionnaire is administered to obtain information on history of hypertension, other CVD risk factors, and health behaviors (eg, smoking, alcohol drinking, physical activity, and sodium and fruit and vegetable consumption). Self-reported medication adherence is also assessed using the 8-item Morisky Medication Adherence Scale.^{22, 45, 46} Health-related quality of life is assessed using the 12-Item Short Form Survey.

Three BP measurements are obtained at each clinic visit using a standard protocol recommended by the AHA.⁴⁷ BP is measured with the participant in a seated position after 5 minutes of quiet rest. In addition, participants are

Table IV. Study measures and data collection schedule

Measures	Screening/ baseline visits		Follow-up visits				Posttrial follow- up
	BV1	BV2	6 m	12 m	18-m TV1	18-mo TV2	
Informed consent and HIPAA authorization	X						
Questionnaire							
Medical history	X		X	X		X	
Sociodemographics		X	X	X		X	
Lifestyle factors		X	X	X		X	X
Adherence and adverse events		X	X	X	X		X
Physical measures							
Blood pressure	X	X	X	X	X	X	X
Weight		X	X	X	X		X
Height		X					
Health-related quality of life							
12-item Short Form Survey		X	X	X	X		X
9-item Patient Health Questionnaire	X		X	X	X		X
Patient satisfaction			X		X		X
Implementation indicators	X	X	X	X	X	X	X
Electronic health records (continuously)		X	X	X	X		X

BV, screening/baseline visits; TV, termination visits at month 18.

advised to avoid alcohol, cigarettes, coffee/tea, and exercise for at least 30 minutes before their BP measurement. BP measurements are obtained objectively using an automated measurement device (model HEM-907 XL; Omron Healthcare, Lake Forest, IL), and 1 of 4 cuff sizes (pediatric, regular adult, large, or thigh) is chosen according to participant's arm circumference.

The appropriateness and feasibility of our intervention program were assessed among FQHC leadership, providers, and patients using qualitative research methods and were used to improve implementation strategies. Other implementation outcomes, including adoption, acceptability, and fidelity, are obtained using focus group, survey, and administrative data throughout the study (Table III).⁴⁸ The fidelity of the stepped-care intensive-treatment algorithm is measured by (1) intensification of antihypertensive treatment (titrating up dosage or adding in new medication) and (2) patients' adherence to medications. Additional fidelity outcomes include the proportion of health coaching sessions attended out of the expected number, the proportion of home BP measurements conducted out of the expected number, and the proportion of provider visits attended out of the expected number. Medication intensification is assessed as the proportion of visits with medication intensification out of the number of visits when the protocol would recommend intensification and also be assessed within each 6-month period to compare to that of the usual care group. Adoption is assessed from provider and administrator interviews and consists of the proportion of intervention clinics adopting the BP treatment goal and protocol; the proportion of intervention clinics adopting the multifaceted implemen-

tation strategy, overall and by strategy; and the proportions of providers and staff in each FQHC completing training sessions for proper BP measurements (out of all staff), the treatment algorithm (out of all providers), and health coaching (out of invited staff). *Acceptability* is defined as satisfaction with the multifaceted strategy among patients, providers, and health coaches and is measured using surveys throughout the study. Sustainability is evaluated by the maintenance of protocol-based treatment, team-based collaborative care, BP audit and feedback, and health coaching by FQHC clinics and provider teams, and home BP monitoring, adherence to medication and lifestyle change, and BP control among patients at a posttrial follow-up visit 12 months after external National Institutes of Health funding ends.

Adverse events

All serious adverse events (SAEs) and selected adverse events (AEs) are collected and reported to the Tulane University Institutional Review Board. SAEs are defined as events that are fatal or life-threatening, result in significant or persistent disability, require or prolong hospitalization, or are important medical events that investigators judge represent significant hazards or harm to research participants. In addition, the following AEs are reported if they result in an emergency room/department evaluation, regardless of whether or not they require hospitalization: injurious falls, syncope, arrhythmia, new or worsening heart failure, stroke or transient ischemic attack, and electrolyte abnormalities. We also monitor occurrences of acute kidney injury or acute renal failure if they are noted on admission or occurred during a hospitalization and are reported in the hospital discharge summary as a primary or

main secondary diagnosis. Participants are queried for SAEs and selected AEs at all clinic visits.

Data analysis and statistical power

We will test the hypothesis that there is a greater reduction in mean BP in the intervention group than in the enhanced usual care group using a mixed-effects regression analysis with participants and clinics as random effects and intervention group, time, and the group-by-time interaction as fixed effects. Binary outcome group differences will be tested using adjusted χ^2 tests and will be analyzed using generalized estimating equations.^{49,50} For primary analyses, data will be assumed to be missing at random, and key baseline variables will be adjusted that are imbalanced between intervention and usual care groups and that are associated with missingness. In sensitivity analyses, multiple imputation for missing data will be conducted using the Markov chain Monte Carlo method, and effect size estimates with and without multiple imputation will be compared.⁵¹

The cluster randomized IMPACTS trial with a total of 1,260 participants (average of 35 in each clinic) has 90% statistical power to detect a 5.0-mm Hg difference in systolic BP at a 2-sided significance level of .05. Clustering by clinic was accounted for, and an intraclass correlation coefficient of 0.063 was used based on prior work.⁵² Furthermore, an 80% follow-up rate and a standard deviation of systolic BP of 17.0 mm Hg were assumed.⁵² For the secondary outcomes, we have 90% statistical power to detect a 4.88-mm Hg difference in diastolic BP and a 15% difference between groups in the proportion of systolic BP <120 mm Hg.

Protection of human subjects

The IMPACTS study has been approved by Tulane University Institutional Review Board, and the study is being conducted following strict guidelines for the protection of rights of human volunteers. An independent data and safety monitoring board monitors safety, study conduct, and scientific validity and integrity of the trial and provides recommendations to the funding agency on trial continuation. Informed consent is signed by all study participants at screening. Two separate consent forms are used based on clinic intervention group assignment, and participants consent to all study activities in their clinic. The proportion of those willing to consent will be reported, and characteristics of those who provide consent will be compared to those who refuse to participate to assess generalizability.

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the drafting and editing of the paper, and its final contents.

Study enrollment and timeline

Enrollment began in June 2018 with 854 study participants recruited by March 2020. We anticipate completing recruitment by the end of 2020.

Conclusions

The IMPACTS study is novel in several respects. First, it is the first study to disseminate and implement the SPRINT study findings in real-world clinical practice and to study whether a SPRINT-like BP treatment target can be achieved in predominantly low-income patients with hypertension. Second, the effectiveness-implementation hybrid design blends clinical effectiveness and implementation trials to support more rapid translation into clinical practice. Third, because the study addresses patient-centered issues and is implemented within the resource-limited FQHC setting, the study findings could be readily scaled up to other primary care settings. Fourth, team-based collaborative care includes an increased role for nurses and pharmacists with appropriate supervision from primary care providers. This health care delivery model will increase efficiency and reduce costs, thus improving the likelihood of adoptability and sustainability over time.

The IMPACTS study is very timely and has important public health and clinical implications. It will provide crucial information on developing multifaceted implementation strategies to achieve more intensive BP control in populations with health disparities. If proven effective, the multifaceted intervention strategies can be adopted by other low-resource primary care settings for more intensive BP control, eliminating health disparities and reducing the BP-related disease burden in ethnic minority and low-income populations in the United States and around the world.

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Appendix. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ahj.2020.08.009>.

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