Blood Pressure Visit Intensification Study in Treatment: Trial design

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Background There is a presumption that, for patients with uncontrolled blood pressure (BP), early follow-up, that is, within 4 weeks of an elevated reading, improves BP control. However, data are lacking regarding effective interventions for increasing clinician frequency of follow-up visits and whether such interventions improve BP control.

Methods/design Blood Pressure Visit Intensification Study in Treatment involves a multimodal approach to improving intensity of follow-up in 12 community health centers using a stepped wedge study design.

Discussion The study will inform effective interventions for increasing frequency of follow-up visits among patients with uncontrolled BP and determine whether increasing follow-up frequency is associated with better BP control. (Am Heart J 2015;170:1202-10.)

Background

Hypertension is the most common medical diagnosis by physicians at office visits.[1,2] Hypertension is also a major mutable risk factor for cardiovascular disease[1,3] and the leading determinant of black-white disparities in cardiovascular morbidity and mortality.[4] Despite long-standing national guidelines for the management of hypertension, blood pressure (BP) control remains suboptimal. Nationally, BP is controlled among only 64% of adults under treatment for hypertension.[5] Black-white disparities in rates of BP control are seen nationally[6] and also within federally qualified health centers.[7,8]

National guidelines, including those from expert committees for the Joint National Committee (JNC VII and VIII) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, address when to initiate BP treatment, which medications to use, and the frequency of follow-up visits for patients not at target BP goal.[3] The recommendation to schedule patients with uncontrolled BP for a follow-up visit within 4 weeks of the last office visit is largely based on observational data and expert opinion.[9,10] Furthermore, many clinicians do not adhere to this recommendation—patients with uncontrolled BP are often seen less frequently than monthly.[9,11-13] Interventions are needed to promote implementation of this increased visit frequency component of the guidelines into practice. More importantly, experimental data are needed to confirm observational data that increased office visit frequency improves BP control.

Study aims and hypotheses

The aim of this study, entitled Blood Pressure Visit Intensification Study in Treatment (BP-VISIT), is to determine whether a multimodal intervention designed to increase office visit frequency for patients with uncontrolled BP will lead to improvement in BP control rates. Using the theory of planned behavior as our conceptual model,[14] our central hypothesis is that an intervention that targets clinician awareness, attitudes, norms, perceived control, and routines relevant to this recommendation will increase visit follow-up frequency on patients with uncontrolled BP. Our secondary hypothesis is that this intervention, by increasing visit frequency, will improve BP control. The specific aims and hypotheses of the BP-VISIT trial are shown in Table I.

Methods

Study design

The study design is a stepped wedge cluster-randomized trial (SWCRT). The target population is clinicians at 12 community health centers (CHCs), including federally qualified health centers that participate with Clinical Directors Network (CDN), a primary care practice-based

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Table I. Aims and study hypotheses

Aim 1: To implement the JNC recommendation for monthly visits for hypertensive patients with uncontrolled BP using a theoretically informed, empirically grounded, multimodal quality improvement intervention.
Hypothesis 1.1: The intervention will improve hypertension visit frequency among patients with uncontrolled BP.
Aim 2: To improve BP control and reduce disparity in BP through implementation of monthly visits.
Hypothesis 2.1: The intervention will improve BP control among patients with uncontrolled BP.
Hypothesis 2.2: The intervention will decrease black-white disparity in BP control.
Aim 3: To assess potential mediators and moderators of the intervention.
Hypothesis 3.1: Changes in clinician perceptions will mediate effects on visit frequency.
Hypothesis 3.2: Clinician use of template/order set will mediate effects on visit frequency.
Hypothesis 3.3: Visit frequency and medication intensification will mediate effects on BP.
Hypothesis 3.4: Patient insurance, comorbidity, resistant hypertension, and high baseline values will moderate effects on visit frequency.

research network (PBRN). When there is not perceived equipoise by practices, the stepped wedge design enables all practices to receive the intervention. This facilitates practice recruitment and retention into the study and permits study of a delayed treatment effect. The 12 CHCs are randomly assigned in blocks of 4, to when they receive the intervention, with early and delayed groups, and also the blocks separated by 6 months. This results in 4 intervention periods, with 2 CHCs participating in first and last periods, 4 in the 2 middle periods, and follow-up periods of up to 30 months (Figure 1).

Funding support and ethics approval

This trial is funded by the National Heart, Lung and Blood Institute (NHLBI). Ethical approval was obtained from the University of Rochester, CDN, and New York University institutional review boards. We obtained waivers of consent and for Health Insurance and Portability Accountability Act restrictions for patient participants. Such waivers are relevant for conduct of pragmatic studies where there is minimal risk to patient participants, the practice is the unit of intervention, and the study could not be feasibly implemented if individual informed consent was required.[15,16] The study is registered at www.ClinicalTrials.gov (NCT 02164331).

Data safety and monitoring board

An external data safety and monitoring board was established before enrollment. The 3 members include a biostatistician and 2 physicians with extensive experience in clinical trials for BP control, one who serves as the board's chair. The first data safety and monitoring board meeting included review and discussion of BP-VISIT's Charter, overview of study activities, protocol review, and recommendations, determining the frequency of meetings and interim analyses and discussion of trial monitoring and early stopping rules.

Power and sample size

We estimated sample size using the method described by Hussey and Hughes for SWCRTs.[17] A total of 12 CHCs will be randomly assigned to implement the intervention at 1 of 4 phase-in periods of 6 months and postintervention follow-up of up to 30 months (Figure 1). With an estimated minimum of 200 patients satisfying eligibility criteria in each CHC, the study is sufficiently powered to test the study hypotheses including moderation effects. We used the SE and intraclass correlation (ICC) information from a prior NHLBI-funded cluster randomized controlled trial conducted by the authors (J.T. and G.O.).[18]

For the primary outcome in aim 1, the study has 80% power to detect a 0.35 difference in number of visits based on a 2-sided test with $\alpha = .05$, with the assumption of an average number of 3 visits (SE 0.38) for the preintervention within 6 months and an ICC of 0.05. For the secondary outcomes in aim 2, assuming that the systolic BP (SBP) and diastolic BP (DBP) are 150.7 (SE 16.7) and 91.0 (SE 10.6), respectively, the study has 80% power to detect a 1.5 mm Hg difference in SBP and 1.0 mm Hg difference in DBP, again based on a 2-sided test with $\alpha = .05$ and ICC of 0.05. Although this power exceeds clinically relevant BP reductions, it facilitates assessment of moderation effects including clinically relevant reductions in subgroups, particularly self-pay patients where an increased number of visits could be a financial burden. For this 10% of the cohort, we will have 80% power to detect a clinical relevant 4.6-mm difference in SBP.

Recruitment and eligibility

Practices are recruited through the CDN (www.CDNetwork.org), a primary care PBRN recognized by the National Institutes of Health as a best-practice Clinical Research Network and selected by the Agency for Healthcare Research and Quality as a Center of Excellence for Practice-based Research and Learning. Table II shows practice, clinician, and patient eligibility criteria. Based on CDN's experience, we anticipate >90% participation by clinicians.

Randomization and blinding

An offsite study statistician at the University of Rochester will conduct randomization using computer-generated randomization of the practiced based on CHC study identification number. Analysis will be conducted with blinding of when the intervention occurred.