

Hypertension Intervention Nurse Telemedicine Study (HINTS): Testing a multifactorial tailored behavioral/educational and a medication management intervention for blood pressure control

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Background Only 31% of Americans with hypertension have their blood pressure (BP) under effective control. We describe a study that tests 3 different interventions in a randomized controlled trial using home BP telemedicine monitoring.

Methods A sample of hypertensive patients with poor BP control at baseline (N = 600) are randomized to 1 of 4 arms: (1) control group—a group of hypertensive patients who receive usual care; (2) nurse-administered tailored behavioral intervention; (3) nurse-administered medication management according to a hypertension decision support system; (4) combination of the 2 interventions. The interventions are triggered based on home BP values transmitted via telemonitoring devices over standard telephone lines. The tailored behavioral intervention involves promoting adherence with medication and health behaviors. Patients randomized to the medication management or the combined arm have their hypertension regimen changed by the study team using a validated hypertension decision support system based on evidence-based hypertension treatment guidelines and individualized to patients' comorbid illnesses. The primary outcome is BP control: $\leq 140/90$ mm Hg (nondiabetic) and $\leq 130/80$ mm Hg (diabetics) measured at 6-month intervals over 18 months (4 total measurements).

Conclusions Given the increasing prevalence of hypertension and our inability to achieve adequate BP control using traditional models of care, testing novel interventions in patients' homes may improve access, quality, and outcomes. (Am Heart J 2007;153:918-24.)

Despite the increased incidence of multiple hypertension-related diseases, the availability of respected evidence-based guidelines, only a third of all US hypertensive patients have their blood pressure (BP) under adequate control.¹ Given our inability to achieve adequate BP control using traditional clinic-based physician visits and the potential barriers patients face in

obtaining healthcare, interventions that use home BP telemonitoring have the potential to enhance access and improve outcomes for adults with hypertension. We discuss a clinical trial that uses home BP telemedicine monitoring to identify patients with inadequate BP control and then use those values to trigger the intervention.

Most primary care providers know the importance of hypertension; however, there is strong evidence that physicians' threshold for initiating medication changes or increasing dosage is approximately 5 to 10 mm Hg above currently accepted guidelines.^{1,2} This tendency of higher threshold has been termed 'clinical inertia.'³ Patient treatment nonadherence is another major barrier to hypertension management.^{4,5} Barriers to adherence such as adverse effects, health literacy, and regimen complexity often are not addressed.^{6,7} Strategies designed to overcome clinical inertia and improve patients' treatment nonadherence may improve rates of BP control.

This randomized clinical trial will determine which of 3 nurse-administered interventions, all triggered by

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Table 1. Overview of the proposed study design

Intervention arm (sample size)	Usual care (n = 150)	Tailored behavioral intervention (n = 150)	Medication management (n = 150)	Combined intervention (n = 150)
Intervention components	a. Provider-driven care, based in clinic, no special hypertension programs	a. Home BP monitoring evaluated by nurse b. 11 tailored behavioral modules	a. Home BP monitoring evaluated by nurse b. Medication management intervention	a. Home BP monitoring evaluated by nurse b. 11 tailored behavioral modules c. Medication management intervention

home BP values and delivered in the patients' home, is most effective in improving BP control. To our knowledge, this is one of the largest studies examining the use of home BP monitors in a telemedicine format and using the information obtained from home monitoring to guide clinical decisions.

Design, setting, and recruitment

The Hypertension Intervention Nurse Telemedicine Study trial is testing 3 nurse-administered interventions in a 4-group design: (1) usual care, (2) tailored behavioral intervention, (3) medication management intervention using a validated decision support system (DSS), and (4) combined behavioral and medication management intervention (Table 1). Potentially eligible individuals are selected from patients who are enrolled in primary care in 1 of the 3 Durham VA general internal medicine clinics; who have a diagnosis of hypertension based on *International Classification of Diseases, Ninth Revision*, codes; and who are using a BP-lowering medication. An additional inclusion criterion is that patients are required to have inadequate BP control based upon the average of the prior 12-months of clinic BP recordings obtained from electronic medical records. Patients are excluded if they are receiving dialysis; received an organ transplant; hospitalized for stroke, myocardial infarction, coronary artery revascularization, a diagnosis of metastatic cancer, or dementia. Patients are also excluded if they do not have a home telephone or reside in a nursing home, if they receive home health care, or if they have severely impaired hearing or speech. There is 1 laboratory exclusion: serum creatinine >2.5 mg/dL or no creatinine laboratory result in past year. Applying these criteria yields approximately 2700 patients available for enrollment (see Figure 1).

Once patients are identified, their primary care provider sends them a letter describing the study. A research assistant then contacts patients and arranges an in-person meeting at the patients' next primary care provider visit to obtain informed consent and conduct a baseline interview. Consenting patients are then randomized to 1 of the 4 arms using consecutively numbered envelopes; randomization is stratified by

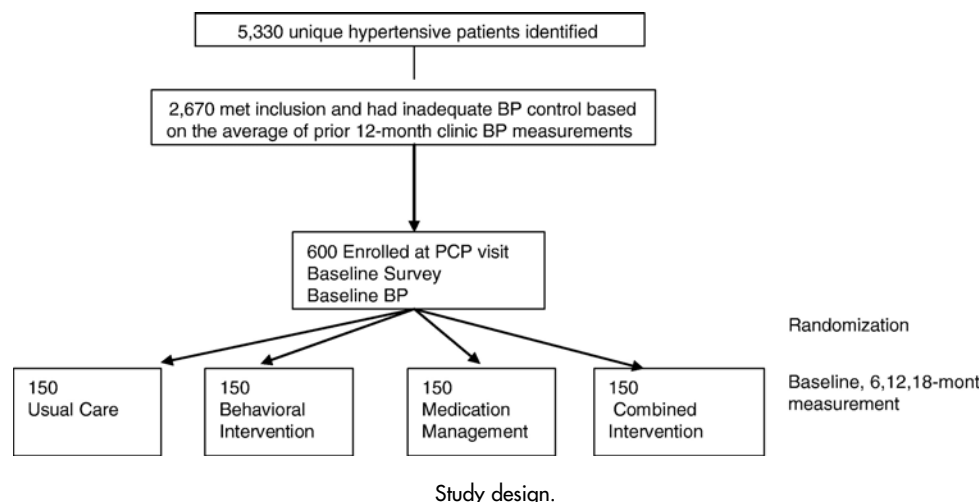
diabetic status. Participants are reimbursed \$10 each for baseline visit and the 3 subsequent 6-month BP measurements (\$40 total). The Durham VAMC Institutional Review Board has approved this study.

The 3 primary care clinics are staffed by 28 internal medicine faculty physicians and 10 midlevel providers. The Durham VAMC serves a diverse patient population; it is composed of approximately 40% African American patients. We will recruit 600 patients, and all patients will be followed for 18 months.

Telemedicine and home BP monitoring

Encouraging patients to use home BP monitors provides objective information to motivate patients to control their hypertension. Home monitoring also provides documentation of the effects of medications and allows for faster therapy adjustment, which may improve patient adherence to prescribed treatments and subsequent BP control.⁸⁻¹⁰ All patients randomized to an intervention arm are provided a wireless home BP monitor (A&D Medical Digital Blood Pressure, Model UA-767PC) and telemedicine device (Carematix Inc, Model #102). The telemedicine device connects to a telephone line like an answering machine. Patient's responses are sent automatically via a toll-free telephone number to a secure server. The nurse can access measurements from the server on a daily basis. By centralizing monitoring and medication management in this way, we believe we may have a greater ability to implement medication recommendations and overcome barriers to care.

Blood pressure measured at home averages 6-8 systolic BP/5-6 DBP mm Hg lower than values obtained during a routine clinic visit.¹¹ We have chosen to trigger the interventions based on a 2-week average home BP of $\geq 135/85$ for nondiabetics¹² and $\geq 135/80$ for diabetics. Because of the lack of standards for target home BP values for patients with diabetes, the home BP monitoring values used to trigger the intervention for these patients were based upon a panel of hypertension clinicians' recommendations. Deciding not to treat to 5 mm Hg lower values at home was based partially on the concern of treating diastolic BP too low, thereby resulting in symptomatic hypotension.

Figure 1

The definition of poor BP control detected by home monitoring is based on an average biweekly BP (minimum of 6 values) that falls above the accepted range. Above average BPs trigger the appropriate intervention depending on group assignment. A safety alert is activated if 2 consecutive home BP measurements are greater than 175/105 mm Hg and separated by a 12-hour period. In this instance, a nurse contacts the patient and initiates the safety protocol.

Tailored behavioral intervention

A multifaceted, comprehensive intervention is being implemented because no single behavioral factor has been shown to consistently improve BP control. The intervention consists of 11 tailored health behavior modules focused on improving hypertension self-management. The use of tailored feedback allows the nurse to address issues that are specifically relevant to a particular patient¹³ but in a standardized way.

Hypertension knowledge/risk perception

Patients who do not accurately understand the risks associated with poor BP control receive information from the nurse on the importance of maintaining BP control. Counseling is tailored to individuals who are diabetic,¹⁴ African American,^{15,16} recently diagnosed, and/or have hypertensive relatives.^{17,18} Risk information is presented using relative risk reduction models, which have been reported to be the most accepted method of presenting risk information for hypertension.^{19,20} If identified by the patient as a confidant, a family member/friend may also have the patient's hypertension regimen explained to them.

Memory

Patients identified as having a memory deficit are provided mnemonic strategies to help remind them of the need to take their hypertensive medication consistently and in a timely manner. Memory adherence strategies provided include cueing (eg, pairing taking medication with an established behavior such as brushing teeth) or monitoring (eg, using a calendar to track medication taking). We also provide a weekly pill reminder container.

Social/Medical environment

Individuals who lack adequate social support receive information about potential hospital and community resources, including a toll-free number to assist them in obtaining medications and getting to their doctor appointments.

Patient-provider relationship

For those patients who are classified as having poor patient-provider communication, the nurse explores 4 areas of potential problems: patients feeling rushed, feeling that their provider does not listen to them, not understanding/forgetting information, and feeling that their provider does not involve them in their care. The nurse problem-solves with patients and sets goals of what is reasonable to accomplish at the patient's next provider visit.

Adverse effects of antihypertensive medication

At each phone call in which the patients' BP is out of control, the nurse queries the patient about any hypertension medication adverse effects. If a patient is

experiencing one, the nurse discusses the issue with the patient. The nurse contacts the study physician if a patient reports any potentially life-threatening side effects after instructing the patient to call 911 if the problem represents an emergency.

Health behaviors

Patients are provided the evidence-based recommendations regarding hypertension-related behaviors and are advised on how to reduce behavior risk factors. All patients in our study receive information on caffeine use, salt intake, weight, stress reduction, smoking cessation, and alcohol use. Verbal information is reinforced with mailed handouts.

Diet

The nurse discusses the Dietary Approaches to Stop Hypertension diet, which has been found to lower BP²¹ and offers an National Heart, Lung, and Blood Institute-produced handout to reinforce what is discussed.

Exercise

The nurse assesses patients' stage of change for physical activity. Once a patient's stage of change is identified, the nurse can help facilitate the patient's progression and movement through stages.²² For patients not exercising and not yet ready to change their physical activity level, the nurse explores the reasons for the lack of activity. The nurse provides information about the benefits of increasing physical activity. Among patients who are thinking about changing their activity levels or already changed them, the nurse reinforces these behaviors and problem-solves and addresses any foreseeable barriers that may limit their abilities to start or maintain an exercise regimen.

Smoking

The nurse assesses smokers' stage of change for smoking and tailors patients' progress to cessation. Barriers to initiating and maintaining smoking cessation are explored, and benefits of smoking cessation are emphasized. Local resources including a smoking cessation clinic and medications are provided to patients.

Alcohol

Among those individuals who have one or more drinks a week, the nurse provides information and counseling regarding the relationship between alcohol and hypertension. The nurse also provides local alcohol-related resources.

Stress reduction

This module discusses the relationship between stress and BP and evaluates symptoms related to stress levels. Ways to cope with stress including the benefits of sleep and relaxation/meditation are discussed.

Table II. The Hypertension Intervention Nurse Telemedicine Study behavior module schedule

Encounter 1	Opening, medications, closing
Encounter 2	Medications, side effects, memory
Encounter 3	Medications, side effects, diet
Encounter 4	Medications, side effects, exercise
Encounter 5	Medications, side effects, weight
Encounter 6	Medications, side effects, knowledge
Encounter 7	Medications, side effects, stress, memory
Encounter 8	Medications, side effects, decision making
Encounter 9	Medications, side effects, social support
Encounter 10	Medications, side effects, smoking
Encounter 11	Medications, side effects, alcohol
Encounter 12	Medications, side effects, memory
Encounter 13	Medications, side effects
Encounter 14	Closing

Behavioral intervention schedule. A unique aspect of the tailored behavioral intervention is that the modules are activated only if patients have inadequate home BP control in the prior 2 weeks. If BP control is inadequate, the nurse contacts the patient and discusses material for that particular encounter. The activation frequency of each module varies depending upon how often the patient has poor BP control. Each intervention encounter typically involves 3 to 4 modules (eg, if encounter 2 was activated, the nurse could activate the medication management, side effects, and memory modules, depending on the patients' needs). Each encounter lasts approximately 5 to 10 minutes (see Table II for a schedule of interventions). Once a behavioral encounter occurs, the nurse waits 6 weeks before activating another behavioral intervention. Those patients who maintain adequate BP control will not activate the intervention but will trigger a contact every 6 months to reinforce their positive behavior.

To ensure that the tailored information is standardized, the nurse uses an intervention software application that contains predetermined scripts and patient-specific tailored algorithms. In addition, the intervention application tracks information discussed at each phone call to provide a full understanding of the tailored intervention processes. The duration of each call is recorded for later use in cost-effectiveness analyses. Patients are also able to telephone the nurse with questions related to their hypertension.

Medication management intervention. The medication management intervention is based upon the Assessment and Treatment of Hypertension: Evidence-Based Automation-Hypertension (ATHENA-HTN) program, which was developed to interface with the Veterans Affairs (VA)'s computerized medical record.²³ Unique features of this system include its strong evidence base (protocols are based on a combination of the Joint National Commission 7 and VA guidelines), its ability to tailor recommendations to patients' comorbid illnesses,

and its ability to rapidly summarize hypertension-relevant information for clinicians at the point of care in the VA's Computerized Patient Record System. Many of the clinical rules are based on the following treatment principles: encourage use of thiazide diuretics, which have established effectiveness in reducing long-term morbidity and mortality; select drug partners with favorable interactions; avoid drug partners with potential adverse interactions; avoid drug partners that do not have added efficacy; in patients with additional diseases, select drugs that are appropriate for dual effects; avoid drugs that may aggravate other health problems; and, alert clinicians to potential withdrawal syndromes.

A nurse (supervised by a physician and working within primary care) implements the DSS-generated recommendations based on home BP values. The ATHENA-HTN is a software system that is populated with patients as they are randomized to the medication management arm and combined arm (randomization is rolling). The ATHENA-HTN is connected to the VA's computerized medical record and pulls information on a daily basis (eg, current medications, medical allergies/adverse reactions, laboratory values, diagnostic codes, contraindications to specific therapy, and BP values). If a BP alarm is activated based upon an average of 2-week home BP values, a recommendation is generated immediately. The recommendation is tailored to the patient based upon data from the patients' medical electronic records. Before a change in therapy is made, the nurse examines the patients' medication records to ensure that the patient has been adequately refilling their prescriptions as well as to determine that there are no recent changes in the individuals' hypertension medication. If there is no other explanation for the patients' high BP, the nurse communicates the recommended change to the patient. The study physician generates a note in the patient's medical record and writes an electronic prescription to ensure that the patient has a sufficient quantity of medication or is prescribed any new medication. Once a medication change is completed, the nurse examines VA pharmacy records to verify the patient has received the new medication. The nurse calls the patient 3 weeks after the medication change to assess if there are any adverse effects or patient questions. No additional change in medication will occur for another 6 weeks to allow adequate time for the medication to work unless a BP safety is activated.

Combined (behavioral intervention and medication management). The combined intervention is activated when a patient's BP control is inadequate based upon values obtained from the home BP telemedicine monitor. The nurse initially addresses hypertension medication change based upon the DSS. The behavioral intervention is then activated following the schedule in [Table II](#).

Usual care group. Patients in usual care receive primary care and management of hypertension according to the discretion of their primary care provider. There are no current disease management programs for hypertension, recording and monitoring of home BP, or telephone interventions active in the Durham VA primary care clinics. A Research Assistant blinded to group assignment contacts patients at the 6-month intervals to complete outcome assessment. Usual care patients receive no contact with the intervention nurses.

Study measures

Baseline. Detailed information about the clinical aspects of each patient is obtained using electronic medical records review including patients' most recent body mass index, dates of primary care visits, current medications, and diagnostic codes for visits. An adapted Hypertension Beliefs Questionnaire²⁴ is used to examine the patient's perceived risk associated with hypertension. Self-reported hypertension adherence is assessed using a 4-item measure.²⁵ The Rapid Estimate of Adult Literacy in Medicine²⁶ is used to measure health-related literacy, and memory is assessed as having self-reported challenges remembering to take one's medication. Smoking habits, alcohol use, diet, and the amount of stress and exercise are assessed by patient responses to survey questions. Patients are asked to list adverse effects experienced that are associated with their antihypertensive medication from a standard checklist used in clinical trials. Patients' view of their providers' communication behavior is assessed with a validated measure.²⁷

Primary outcome. The primary outcome of the study is BP control measured at baseline, 6, 12, 18, and 24 months using standardized research protocol.²⁸ At each measurement point, 2 BP measures are obtained using a digital sphygmomanometer²⁹ after patients have rested for 5 minutes. For each patient's measurement occasion, inadequate BP control is defined as a clinic SBP ≥ 140 mm Hg or a DBP ≥ 90 mm Hg for individuals without diabetes and SBP ≥ 130 mm Hg or a DBP ≥ 80 mm Hg for individuals with diabetes according to the JNC VII/VA guidelines.^{1,30} Blood pressure is measured by RAs who are blind to patient group assignment.

Analyses

The primary hypotheses are the following: (1) Patients who receive only the *behavioral* intervention, *medication* intervention, *combined* intervention will show 15%, 15%, and 25% improved rates of BP control, respectively, as compared with the control group over 18 months of follow-up. We plan to use a generalized linear mixed model with a logit link to address the main study hypotheses.³¹ Fixed effects in the model will include intervention group, time, and the two-way interaction of group and time; the model will also include patient-level random effects to account for correlation

between patients' repeated measures over time. The proposed analyses focus on an intervention group by time effect in the generalized linear mixed model. In this analysis, we accounted for anticipated improvement in BP control among the usual care group. We will examine the slopes for each intervention group and compare those to usual care. We anticipate that there will be a significantly greater change in slope in the intervention groups relative to the control group (see Figure 2). In addition to our main intervention group hypotheses, we will conduct secondary analyses to adjust for important baseline covariates in our models. Prespecified variables will include sex, age, duration of hypertension, race, and diabetes status. Analyses will be conducted as intent to treat, and sensitivity analyses will examine the implications of the intent to treat assumption.³²

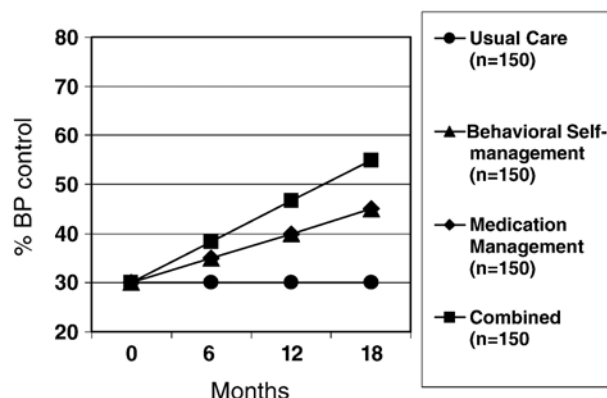
Secondary outcomes

Secondary outcomes of interest in this study include knowledge and perceived risks associated with hypertension. Compared with patients in the usual care and medication management groups, we hypothesize that patients in the tailored behavioral intervention will have greater knowledge and perceived risks associated with hypertension. Knowledge and perceived risks is a continuous measure derived from the modified patient's hypertension beliefs questionnaire.²⁴ Because the measure is assessed at multiple time points for each patient (baseline, 6 months, 12 months, and 18 months), we plan to use a linear mixed effects model for our analysis.

Medication adherence will be assessed using prescription refill records.³³ Using the method validated by Steiner and Prochazka,³⁴ we will calculate a Med-Out index that will be equal to (number of days without medication in the observation period) / (total number of observation days). We will calculate the Med-Out for each antihypertensive medication and create an averaged, summary pill refill value. Treatment differences in mean rates of adherence will be examined with a linear regression model.

Sample size and statistical power. An enrollment criterion is that patients must have inadequate BP control based on clinic BP values over the previous year. From our pilot data, however, we estimate that approximately 30% of patients will have their BP in control at the baseline BP assessment by the RA. Based on results from previous studies, we hypothesize that the sample of patients receiving either of the individual interventions will increase BP control by 15% over the 18 months follow-up (see Figure 2). Testing this hypothesis translates into testing a treatment by time interaction in a generalized linear mixed effects model. We estimated the necessary sample size empirically through a simulation study. We expect approximately 15% of the enrolled sample to dropout by the end of the study based on our prior studies. For a type-I error of 0.05 and 80% power, we

Figure 2



Expected pattern of results.

require a total of 600 patients to be able to detect a 15% increase in probability of BP control.

Discussion

This study is important for multiple reasons. First, this will be one of the first trials to test a tailored behavioral intervention to improve hypertension adherence head-to-head with a medication management strategy designed to overcome provider inertia. The interventions address both prescribing antihypertensive patterns and changing patients' health behavior and treatment adherence in ways that will enhance generalizability if proven effective. In addition, the trial is also one of the first to use home-based BP measurements to activate an intervention and monitor its effects. Second, patients will be enrolled from primary care clinics where most hypertension treatment decisions are made. Third, the study is one of the largest health behaviors, treatment adherence trials conducted in the United States that will also test long-term effects (18 months). Fourth, we have enrolled over 200 patients thus far, and half are minority patients. Additional strengths of the study include intervention algorithms that can be translated into primary care clinics should they prove to be effective. We are building on previous efforts and testing a novel application of a DSS that has been well developed. We also will assess the costs associated with administering the interventions and examine the policy implications of implementing similar interventions to the large pool of hypertensive patients.

Elevated BP is a major risk factor for cardiovascular disease, and improving BP control levels will decrease morbidity and mortality. Despite the known risk of poor BP control, most adults still do not have their BP under effective control. This study is an important step in testing the effectiveness of 3 interventions to improve

BP control among veterans. If this ongoing intervention is able to achieve levels of BP control similar to those set by national VA goals (or higher), information from this study could directly impact clinical practice.

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