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Take Control of Your Blood pressure (TCYB) study: A multifactorial tailored behavioral and educational intervention for achieving blood pressure control

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Abstract

Objectives—Evaluating a randomized controlled trial involving a tailored behavioral intervention conducted to improve blood pressure control.

Methods—Adults with hypertension from two outpatient primary care clinics were randomly allocated to receive a nurse-administered behavioral intervention or usual care. In this ongoing study, patients receive the tailored behavioral intervention bi-monthly for two years via telephone; the goal of the intervention is to promote medication adherence and improve hypertension-related health behaviors. Patient factors targeted in the tailored behavioral intervention include perceived risk of hypertension and knowledge, memory, medical and social support, patients' relationship with their health care provider, adverse effects of medication therapy, weight management, exercise, diet, stress, smoking, and alcohol use.

Results—The sample randomized to the behavioral intervention consisted of 319 adults with hypertension (average age = 60.5 years; 47% African-American). A comparable sample of adults was assigned to usual care (n=317). We had a 96% retention rate for the overall sample for the first 6 months of the study (93% at 12 months). The average phone call has lasted 18 minutes (range 2 to 51 minutes). From baseline to six months, self-reported medication adherence increased by 9% in the behavioral group vs. 1% in the non-behavioral group.

Conclusion—The intervention is easily implemented and is designed to enhance adherence with prescribed hypertension regimen. The study includes both general and patient-tailored information based upon need assessment. The study design ensures internal validity as well as the ability to generalize study findings to the clinic settings.

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Practice Implications—Despite knowledge of the risks and acceptable evidence, a large number of hypertensive adults still do not have their blood pressure under effective control. This study will be an important step in evaluating a tailored multibehavioral intervention focusing on improving blood pressure control.

Keywords

Behavioral Intervention; hypertension; adherence; tailored; health communication

1. Introduction

Hypertension affects 65 million adults in the United States (1) and the prevalence of hypertension continues to increase (2). Despite the rising prevalence of hypertension (3,4), the subsequent increase in incidence of many hypertension-related diseases, and the availability of respected evidence-based guidelines for effective pharmacologic and non pharmacologic treatments, only a third of all hypertensive patients in the United States have their blood pressure under effective control (<140/90 mm Hg non-diabetics, <130/80 mm Hg diabetics) (1). Although, there are many causes of poor blood pressure control, patient non-adherence to pharmacological and non-pharmacological treatment continue to be significant barriers to successful hypertension management (5-10).

Racial disparity in blood pressure control is garnering increased attention. African Americans suffer a disproportionately large burden of cardiovascular morbidity and mortality in the United States compared to white patients (11). However, the impact of functional health illiteracy (FHI) on blood pressure has garnered less attention. Functional health literacy, defined as the “ability to understand and act on health information” (12), is one of the primary components of comprehension necessary for planning and implementing therapeutic regimens. FHI represents a chief obstacle for traditionally underserved patients to adequately control their blood pressure (13). Over 90 million adults lack the literacy skills needed to effectively function in the health care environment (14). FHI is one of a number of key barriers to following medical and lifestyle hypertension management regimens (13,15). Thus, the current intervention directly targets FHI literacy in a large minority sample of individuals with hypertension.

The study also addresses other factors that may contribute to poor blood pressure control (15,16), particularly factors related to hypertension regimen adherence. Hypertension regimen nonadherence can take many shapes and includes not adequately engaging in recommended behaviors such as exercising, dieting, and taking medications as recommended as well as engaging in nonhealthy behaviors such as smoking and excessive smoking. We posit that proven patient-focused strategies for augmenting blood pressure control requires a systematic approach and includes behavior modification (e.g., diet, exercise, smoking, alcohol use, medication use), knowledge (e.g., accurate risk perception), adequate cognitive function (e.g., memory and comprehension), and support (e.g., adequate resources) (15,16).

Given the lack of adequate blood pressure control observed within the United States using traditional office-based physician visits, interventions that use novel methods for the delivery of quality healthcare could increase the effectiveness of hypertension management while containing costs for adults with hypertension. Research is needed to determine the degree to which these interventions can be integrated into primary care and their effectiveness among hypertensive adults. We discuss a nurse-administered, patient tailored behavioral/educational intervention that can be administered via the telephone.

Few studies have implemented a multidimensional intervention that is tailored to patients' needs and delivered by telephone while based in primary care practices. In addition, prior

studies have rarely examined interventions directed at improving both treatment adherence and subsequent blood pressure control long-term (17). Given that hypertension is a complex, chronic disease, a focus on multiple behaviors over a long-term is likely to be important to reach the United States blood pressure control goals of 50% (18). Our study builds upon the strengths of prior studies and incorporates a self-management component by including a tailored behavioral intervention. The trial also includes a sample large enough to conduct subset analyses to examine whether certain groups (e.g., African Americans or individuals who are functionally illiterate) differ by intervention and a follow-up period of 24 months to examine the long-term benefits associated with both interventions.

2. Methods

The Take Control of Your Blood pressure (TCYB) trial is testing a tailored behavioral/educational intervention. Potential subjects were identified through a medical electronic database as having a diagnosis of hypertension by an outpatient diagnostic code. Once the patients were identified, research assistants sent patients letters signed by their primary care provider requesting participation in the study. A research assistant then contacted patients and arranged an in-person meeting at the patients' next primary care provider visit to obtain informed consent and conduct a baseline interview where initial needs were assessed. The needs assessment conducted by the research assistant included evaluating such issues as adequate resources, memory, hypertension knowledge, and risk perceptions. Consenting patients were then randomized to usual care, tailored behavioral intervention alone, home blood pressure monitor alone, or both tailored behavioral intervention and home blood pressure monitor. For the purpose of this study, individuals receiving the behavioral intervention (behavioral alone or combined with home blood pressure monitoring) were compared to those not randomized to the behavioral intervention (usual care or home blood pressure monitoring alone). Patients enrolled in the study are followed for 24 months. See prior manuscript for further discussion of the study design and the home blood pressure monitoring component of the study. (19)

The reason for collapsing the study's four arms into two and thereby focusing on the behavioral intervention is two fold. Since the initiation of this study, home blood pressure monitoring has become more common; home monitoring alone requires minimal effort, and it often is not construed to be an intervention on its own. Second, the main distinction between the treatment arms relies on an understanding of the theoretical foundation of the behavioral intervention, methods for initiating and maintaining behaviors, and the information technology required to support the tailored behavioral intervention.

2.1. Sample

Potentially eligible individuals were selected from a pool of 7646 unique patients who were seen in one of the two primary care clinics for at least one year; had a diagnosis of hypertension by an outpatient diagnostic code (ICD-9 codes 401.9, 401.0, and 401.1); and were using a hypertensive medication at the time of the baseline visit. The research assistants mailed letters from patients' doctors to potentially eligible patients explaining the study and contacted 1692 by phone to further explain the study; 630 individuals refused participation and 235 patients were excluded for the following reasons: not using or prescribed a blood pressure medication; spouse participating in study; not living in a surrounding eight county catchment area; receiving kidney dialysis; received an organ transplant; planning a pregnancy; hospitalized for stroke, myocardial infarction, coronary artery revascularization, or diagnosis of metastatic cancer in prior 3 months; dementia diagnosis; resident in nursing home or receiving home health care; arm size too large for home blood pressure monitor cuff; or severely impaired hearing or speech. There were no blood pressure requirements to enter the study with exception of the

inclusion criteria discussed above. We enrolled 636 participants. Participants were reimbursed \$25 each for baseline visit and the four subsequent 6-month blood pressure measurements (\$125 total). The Duke Institutional Review Board has approved this study; all patients provided written informed consent.

2.2. Theoretical framework

We used the Health Decision Model (HDM) (20) as the theoretical model for identifying factors to focus on in the tailored behavioral intervention. Through previous studies (15,16,21,22) and a comprehensive literature review, we found that the HDM model is a helpful framework for helping to prioritize what factors to focus on. However, it does not exhaustively include all patient and medical factors that help explain poor blood pressure control in hypertensive patients. Therefore, we expanded upon this model by including patient characteristics such as memory, lifestyle behaviors, and experience of adverse effects associated with antihypertensive medication (15).

In addition to using the expanded Health Decision Model to identify potential factors that may explain hypertension nonadherence and subsequent blood pressure control, we used behavior change theories to provide a framework for understanding behaviors related to blood pressure control. Understanding the factors that hinder or promote health behaviors are central to the Transtheoretical Model (23) of behavioral change. The crux of the model is that behavioral change occurs in a series of temporally ordered, discrete stages. Movement between stages is influenced by the ratio of pros and cons of the problem behavior, self-efficacy, temptations to revert to the problem behavior, and coping mechanisms used to change the problem behavior (24).

The Transtheoretical model posits five discrete stages that reflect one's interest and motivation to alter a problem behavior. *Precontemplation* is the stage in which there is an unwillingness to change a problem behavior or there is a lack of recognition of the problem. *Contemplation* involves weighing the consequences of action or inaction of the problem behavior. At this point, patients are able to discuss the disadvantages and advantages associated with, for example, taking an anti-hypertensive medication to prevent a stroke. *Preparation* is the stage when there is a commitment to change in the near future. Patients express a high degree of motivation towards the desired behaviors and outcomes and patients have determined that the adverse costs of maintaining their current behavior exceed the benefits. Therefore, initiating a new behavior is more likely. Patients have moved from thinking about the issue to doing something about it. *Action* involves altering behavior successfully for 1 day to 6 months. *Maintenance* occurs when one has engaged in the new behavior for at least 6 months. During this stage, the focus is on lifestyle modification to stabilize the behavior change and avoid relapse (24).

The intervention incorporates both behavioral and educational aspects of treatment adherence. Adherence conceptualized as an educational problem involves the development of material and unique teaching approaches to help hypertensive patients learn about their disease and its management regimen. Adherence conceptualized as a behavioral issue employs techniques to foster behavior change (e.g., motivational interviewing, problem solving, positive reinforcement, social support, and coping among others).

The intervention involves tailored telephone counseling targeted for individuals based on their needs (25). Tailored interventions are likely to result in increased efficiency; individuals only receive intervention material that is relevant to themselves and subsequently interventions require less time to administer because only relevant information is disseminated. Patient factors targeted in the tailored behavioral intervention include perceived risk of hypertension and knowledge, memory, medical and social support, patients' relationship with their health

care provider, adverse effects of medication therapy, weight management, exercise, diet, stress, smoking, and alcohol use.

Additional techniques used by the nurse to encourage initiating and maintenance of hypertension-related behavior include explaining things clearly using plain language. Because a large proportion of our sample is functionally illiterate, intervention material is at an 8th grade reading level or lower. The lower literate patients (e.g., 8th grade reading level or less based on the Rapid Estimate of Adult Literacy in Medicine (REALM) (26)) received additional materials in the form of pictorial handouts. Handouts were mailed at the conclusion of telephone encounters to reinforce the telephone conversation and provide a resource. In terms of telephone interactions, the nurse used plain language, avoided medical jargon, vague terms, and terms with different medical and lay terms (e.g., hamburgers instead of red meat). The nurse also tried to emphasize just a couple of key points during each module. In addition, whenever possible, the nurse requested that the patients confirm their understanding of the information.

The behavioral intervention was telephone administered for several reasons. Telephone reminders are quite effective in changing patient behavior (27-29). Telephone interventions also provide an opportunity to reach more patients and these interventions may be more acceptable and convenient than in-person interventions (30). Delivering an intervention by telephone may enhance the intervention's cost-effectiveness, (31,32) primarily due to reduced visit rates. This factor is particularly relevant for our sample because many of the patients are older and have difficulties traveling to the clinic. In addition, as of 2003, most U.S. homes have phones (>97%) (33) making it a useful tool to deliver an intervention.

We are using a nurse to implement the tailored behavioral intervention because evidence supports that nurses increase treatment adherence among hypertensive patients (34) and improve blood pressure control (35-40). Randomized clinical trials have demonstrated that non-physician clinicians are more effective at bringing hypertensive individuals in concordance with national guideline goals (41-45). One mechanism for the success of nurses in improving BP control relates to their training to address non-pharmacological interventions. (46)

The nurse underwent training in aspects of motivational interviewing (47) and in the specific procedures, modules, and algorithms developed for this study. Maintaining or developing motivation and overcoming resistance are key issues for individuals attempting to initiate and change behaviors and these were a focus of the nurse training. The training was interactive, with practice sessions incorporating use of motivation and the developed computer-based modules. To ensure fidelity of the intervention, periodic interventions were examined to ensure consistency and following the prescribed intervention material.

2.2. Intervention modules

A major emphasis of the intervention is initiating and maintaining specific health behaviors related to hypertension. The intervention is organized as telephone encounters that occur approximately every 8 weeks. At each telephone encounter, a core group of modules are potentially activated. These modules include medication problems and adverse effects. Within the medication module, patients are queried about their hypertension medication regimen and whether they are adhering to recommended treatment guidelines. To assess adherence, we asked individuals the following validated question "Have you missed any pills in the past week?" The single question has a sensitivity > 50% of those with low adherence and a specificity of 87% (48). Medication adverse effects are also discussed at each encounter. Additional modules such as social support, knowledge, health behaviors including smoking,

weight loss, diet, alcohol use, stress, and participatory decision making are activated at specific telephone encounters. (see Table 1 for schedule of intervention modules).

2.2.1. Open module/medication management—Each encounter begins with an opening session which involves the nurse reviewing the patients' currently prescribed blood pressure medication, assessing if the participant is familiar with the purpose of the medication, and whether there have been any changes in the use of their hypertensive medications. If the patient does not understand the purpose of their hypertension medication in any encounter or how to take the medication, the nurse explains the purpose of each medication prescribed for that individual. If the patient reports that there has been a change in their blood pressure medications, the nurse queries if their primary care provider is aware of the change. If not, the nurse discusses the importance of informing their primary care provider of changes in their blood pressure medication regimens. The nurse then provides an opportunity for the individual to include a family member or friend to receive an overview of the patients' blood pressure medication treatment. The principle of providing information to others is to help reinforce the patient to take their medications as well as provide an additional source of support and reinforcement if necessary. In addition to orally providing the intervention, the nurse follows up the encounter with a medication calendar to help the patient keep written track of his or her medications.

2.2.2. Adverse effects of antihypertensive medication—The nurse queries patients at every phone call about any specific hypertension medication side effects they may have. If a patient is having a hypertension-medication related adverse effect, the nurse discusses the problem with the patients. The nurse also reminds the patient to discuss these adverse effects with their primary care provider. Any potentially life threatening adverse effect is reported immediately to the provider. The goal is to prevent medication nonadherence by informing patients of common adverse effects and help to facilitate medication change when necessary.

2.2.3. Memory—Patients randomized to the nurse intervention who report they have difficulties remembering to take their medication are provided various mnemonic strategies such as setting an alarm or using a weekly pillbox (49). The nurse conveys the need and importance of taking hypertensive medication consistently and in a timely manner to both the patient and family/friends identified by the patient.

2.2.4. Knowledge/risk perception—Patients who do not accurately understand the risks associated with poor blood pressure control receive information and counseling from the nurse on the importance of maintaining blood pressure control by underscoring the association between hypertension and diseases that come about from poor control. Counseling is tailored to individuals who are diabetic(50-53), African-American (54,55), recently diagnosed with hypertension, and/or have hypertensive relatives (56,57) because these factors confer specific risks for worse health outcomes. The nurse queries patients' knowledge so that the intervention material can be more refined. The nurse explores ways patients may treat their blood pressure other than using medications. Additional areas addressed include how high blood pressure may make patients feel, what high blood pressure may do to one's body, and why it is important to treat high blood pressure.

2.2.5. Participatory decision making—The nature of hypertension requires substantial responsibility by the patient for implementing treatment regimens agreed on during the provider-patient visit. Patients identified as having poor provider relationships receive information on ways to empower patients to interact more productively with their providers. Patients' are queried if there is something they would like to change in regards to their interactions with their provider. Four specific areas are addressed by the nurse: patients

perceiving inadequate time allowed for discussion, not “feeling heard”, not understanding information or forgetting what has been explained, and not feeling adequately involved in their own health care decisions. The nurse provides some suggestions for improvement and then reinforces these suggestions by role playing with the patient for a few minutes on the phone.

2.2.6. Diet—The diet module is provided to all patients randomized to the nurse intervention and begins by the nurse asking the patient to talk about foods they eat in a typical day. This leads to a discussion of sodium and sources of where high levels may be found. This is followed by having individuals think of some ways they may be able to reduce their sodium intake. In addition, the nurse discusses how individuals can determine the sodium contents of food and remind patients of how much sodium they should ingest in a day. Sources of caffeine and the role of caffeine in temporarily increasing blood pressure are also discussed. Supporting material that summarizes the discussion is mailed to the patient. This material includes the Dietary Approaches to Stop Hypertension (DASH) diet, which has been found to lower blood pressure (58-60). Patients are sent additional information about reducing sodium in one's diet, sodium content of some popular fast food menu items, foods containing potassium and caffeine, and how to read nutrition labels.

2.2.7. Weight—The weight module is triggered for anyone with a body mass index (BMI) ≥ 25 . The nurse emphasizes the importance of maintaining a healthy weight and queries individuals as to what stage they are in terms of initiating weight loss (not ready, thinking about it, preparing, or taking action). Weight information is then tailored to individuals' level of change. The nurse uses motivating interviewing techniques to explore why individuals are having difficulties losing weight and explores ways to reduce barriers for each individual. For those preparing to lose weight, the nurse works with the patient to set realistic goals, anticipate potential barriers and prepare responses to them, and ask for support from family and friends. Among those individuals who are currently taking action to lose weight, the nurse reminds them that losing up to 2 pounds a week depending on gender is ideal. The nurse provides further tips to help individuals not only initiate weight loss, but maintain it, set monthly goals rather than daily goals, and how to anticipate and plan for setbacks.

2.2.8. Exercise—In this module, the nurse reviews the benefits of exercise and assesses whether individuals have increased their level of physical activity since enrolling in the study and how much exercise they are currently obtaining. The nurse determines their exercise activity stage and information is then tailored to the reported stage. Individuals reporting they are not ready to change physical activity level are provided a few brief benefits of exercise and the nurse explores with the patient what would motivate them to exercise. For those thinking about changing their activity level, the nurse emphasizes a few benefits and provides examples of sources of physical activities. The nurse also explores with the patient what would motivate them to further change their activity level. Among individuals reporting that they are preparing to change activity levels, the nurse asks the individual to set realistic goals, examines the benefits of exercising, and suggests obtaining support from family/friends. In addition, the nurse explores the individual's potential barriers to actually initiating exercise. Finally, for those exercising, the nurse recommends that they talk to their doctor to determine an appropriate level of activity based upon their age and overall health. The nurse also helps the individual to determine the intensity level of their planned activities as well as setting realistic goals, keeping an exercise diary to track their progress, planning for setbacks and rewarding oneself for meeting set goals.

2.2.9. Social and medical environment—If barriers to care, such as a lack of transportation and cost of care and medications, or social isolation are identified, the nurse assists patients in identifying and using available resources to overcome barriers (e.g.,

community resources). Handout material was developed that provides local, county, and state assistance available to help alleviate these barriers. This material also includes information on where to find inexpensive hypertension medication.

2.2.10. Stress—While there is more evidence that stress increases blood pressure in the short-term, the long-term implications of stress are not clear (61). This module involves the nurse querying patients about their knowledge of the relationship between stress and hypertension as well as how individuals know when they are stressed. The nurse provides some suggestions on how to potentially reduce stress.

2.2.11. Smoking—All individuals are assessed for current smoking status. The nurse highlights the benefits of smoking cessation for those who report they are current smokers. The nurse then determines the individual's stage in terms of considering smoking cessation. Among those not ready to quit, the nurse briefly discusses the benefits of smoking cessation, offers resources available to help smoking cessation, and explores with the patient potential barriers that are prohibiting individuals from cessation. Among those considering quitting, the nurse discusses setting a stop date and obtaining social support to stop, provides information on available smoking cessation programs and resources, discusses the potential cost savings of smoking cessation, and explores possible motivations for patients to stop smoking. For patients reporting they will quit soon, the nurse suggests that they set a smoking cessation date and stick to it. The nurse also discusses what to expect with smoking cessation, the potential use of nicotine replacement products or oral medicines, and what has motivated the individual to take action. For those individuals in the process of quitting, the nurse reviews steps individuals can take to increase their chance at success: continue to ask friends or family for support, be aware of the physical withdrawal symptoms, avoid smoking situations, remind themselves of what motivated them to quit and explore potential barriers that may make it hard to continue smoking cessation.

2.2.12. Alcohol—Women who drink greater than 7 alcohol drinks a week and men who drink greater than 14 a week receive information regarding the relationship between excessive alcohol intake and hypertension. In addition, individuals are cautioned regarding the possible interactions between alcohol and hypertension medications.

2.3.13. Literacy—Literacy was assessed at baseline using the Rapid Estimate of Adult Literacy in Medicine (REALM) was used to measure literacy (62). Patients read aloud from a 66-item list of medical terms arranged in increasing difficulty and is scored as a count of correctly pronounced words with a raw score that can be converted to reading grade estimates. The REALM has high criterion-related validity compared to longer literacy measures (63, 64). Literacy was evaluated as a dichotomous variable with low literacy defined as REALM score, 0–60 (<9th grade level) and adequate literacy defined as REALM score 61–66 (≥9th grade level). This operationalization was based on prior convention and is consistent with findings correlating limited literacy and mortality using this categorization (65).

We did not tailor on health literacy because the easiest way of presenting material generally is the most effective, but the behavioral intervention addressed health literacy using three methods. First, individuals who lacked adequate knowledge regarding their medication (e.g., the purpose or how to take their medication) received specific material regarding their hypertension regimen at each call. Second, whenever possible, we involved patients' significant others as an additional method of supporting the patients' hypertension regimen. Third, we provided supporting/reinforcing material via the mail and used graphics when ever possible; all intervention material was evaluated and was deemed to be less than 8th grade reading level.

2.2.14. Closure encounters—At each encounter's closure, the nurse asks patients to report their most recent blood pressure. If they are not aware of it, the nurse reiterates the importance of knowing one's blood pressure. For those who know their blood pressure, the nurse provides feedback for those with inadequate blood pressure control and further reinforcement for those with adequate blood pressure control.

2.2.15. Patient activated encounter—If a patient had concerns regarding their hypertension treatment, they could also call the nurse.

2.3. Control group

Patients randomized to the control group receive no change in care. However, they are contacted at the six-month and 24-month post baseline evaluation in order to complete the same outcome measures as the other groups. Patients randomized to the control group as well as the intervention group have their blood pressure measured using a standardized protocol at six-month intervals for 24 months (5 total measurement points). The control group receives no contact by the nurse.

2.4. Six-month secondary outcome measure

2.4.1 Self-reported medication adherence—Self-rated adherence was assessed using the four-item Morisky Self-reported Medication-Taking Scale (66). The scale for each item was revised to include the response categories strongly agree, agree, disagree, and strongly disagree. Those individuals who reported strongly agree, agree, don't know, or refused to any of the four items were classified as nonadherent (67). Self-report scores as measured by the same scale used in the current study had a sensitivity of 72% and specificity of 74% for $\geq 80\%$ adherence with antidepressant medication (68).

3.0. Results

The sample randomized to the nurse intervention consisted of 319 adults with hypertension (Mean age = 61 years; 47% African-American), 35% had a 12th grade education or less, and 27% were functionally illiterate ($REALM \leq 60$ (i.e. < 9th grade reading level)). Thirty-four percent of these subjects reported that they had diabetes. The usual care group had similar characteristics (mean age=62; 51% African-American, and 27% were functionally illiterate, 38% had self-reported diabetes) (see Table 2).

3.1. Feasibility

For patients randomized to the nurse intervention, we have maintained a 96% retention rate for the first 6 months of the study (93% at 12 months). The nurse contacts patients every two months; the average length of the first intervention phone call was 16 minutes and ranged from 6 to 47 minutes (standard deviation = 6.1). For encounters 1–4 (the first 6 months of the study), the average phone call took 18 minutes (standard deviation = 17) and ranged from 2 to 51 minutes.

3.2. Frequency of activation

Thus far, the participatory decision making module has been activated for 27% of the patients. In terms of hypertension knowledge, 64% of the individuals lacked adequate knowledge as defined by accurately answering all 7 questions (69), so the nurse discussed the benefits of controlling blood pressure with these patients. In addition to receiving generic information regarding hypertension knowledge, individuals who had diabetes (34 %), minorities (50%), individuals with parents with hypertension (78%), and those with a hypertension diagnosis less than two years ago (11%) received specific information related to these characteristics. Nine

percent of patients activated the social support module and reported having difficulties accessing aspects of their healthcare. For the lifestyle behaviors, 81% activated the weight module, 32% activated the exercise module, 35% activated the stress module, 42% activated the alcohol module, and 14% activated the smoking module.

3.3. Six-month preliminary secondary outcomes

The intervention group had a 9% increase in self-reported medication adherence from baseline (63%) to 6 months (72%) while the increase in the control group was only 1% (67% (baseline) to 68% (6 months)).

3.4. An Example of Two Nurse Phone Intervention Encounters

We describe two intervention encounters. The first participant was a 66-year-old white woman with less than a 9th grade reading level. At encounter three, there were no medication changes. The nurse reviewed the individual's diet. At the follow up call two months later (4th encounter), the individual reported that she was following the recommendations and was watching what types foods eaten and portion sizes; subsequently, she lost weight since her prior call. In encounter four, the participant did not report problems forgetting to take her medication and when queried about exercise, the participant reported that she had been using a treadmill daily - was walking 3–4 miles daily. The nurse encouraged her to continue this behavior and urged her to increase her walking pace as tolerated. Because social and medical barriers were assessed, the subject reported that she asked a brother to buy her a blood pressure monitor because she lives in a rural area without many public places to check her blood pressure. She reported using the home blood pressure monitor 3 times a week. The length of the intervention at encounter 4 took approximately 14 minutes.

The second example was a 69 year-old African American woman with no literacy problems. At encounter four, the participant did not report any recent exercise. The nurse explored why the individual was not exercising and found that the participant had osteoarthritis of the spine and feet, so she was reluctant to do much walking. The nurse explored some possible ways to alleviate her concern and by the next call, the individual reported that she was now walking at a nearby mall with her daughter, had purchased a pedometer, and was keeping a walking log. The individual also had a medication dosage change; her Lotensin was increased to 40 mg/day and the nurse discussed why the medication was increased and what she should expect in terms of potential adverse effects. Because the participant reported forgetting to take her medication, at the nurse's suggestion, she is now using a pillbox for her medications and has not missed any medications in past month. The length of the phone intervention took approximately 15 minutes.

4.0 Discussion and conclusion

4.1. Discussion

This nurse-administered telephone behavioral intervention has early indication of acceptance, feasibility, and efficacy. The intervention has been successfully administered in a low literate (27% functionally illiterate), racial minority (47% African American) sample. Beyond our success in recruitment, our retention rate of 96% at 6 months provides further indication of acceptance of this tailored intervention.

As many as 60% of hypertensive patients discontinue their treatment within the first year of care (70-72), and fewer than 65% remain in therapy after three years (72,73). Of those remaining in treatment, antihypertensive medication adherence varies from 40% to 70% (74-76). Poor medication adherence is likely a contributing factor for as many as two-thirds of all hypertensive patients who have inadequate BP control (7,77-79). Adherent patients have

better health outcomes, even when their medication is a placebo (80). In the current study, we observed that those receiving the intervention had a greater improvement medication adherence – 8% as compared to the control group. We will examine whether this improvement in medication adherence translates into improved BP control and whether rates of adherence differ by literacy levels.

Potential limitations of the current study need to be acknowledged. While we used a self-reported adherence assessed by a valid, reliable measure, (66) there are potential problems of under representing or inaccurately reporting actual medication adherence. Given the lack of a centralized access to medications and prohibitive costs of using electronic medication records (MEMS Caps) and the number of hypertensive medications individuals were using, we have had to rely on a self-report assessment of patients' adherence. However, it is the most commonly used measure of adherence because it is simple, inexpensive, and convenient to use. (81) An additional limitation of the study is the potential lack of generalizability beyond the Southeast United States. However, the people in the Southeastern United States, and African-Americans in particular, experience a higher burden of disease due to hypertension. The continued high prevalence of hypertension and hypertension-related complications of stroke, heart failure, and end-stage renal disease makes these diseases a public health concern for all who reside in this region (82).

4.2. Conclusion

The intervention is easily implemented and is designed to enhance adherence with prescribed hypertension regimen, particularly among those with low literacy. We have observed significant improvements in self-reported medication adherence at 6-months. The study includes both general and patient-tailored information based upon need assessment. Thus, the time required to implement each bi-monthly intervention is approximately 18 minutes. Given the increasing prevalence of older adults and increasing number of complex chronic conditions, interventions that demonstrate improvements across multiple behaviors are essential, particularly if they can be implemented relatively quickly and cost effectively.

4.3. Practice implications

Despite knowledge of the risks and acceptable evidence, a large number of hypertensive adults still do not have their blood pressure under effective control. Our research will produce recommendations that will allow primary care clinic managers to achieve an improved rate of blood pressure control for their patients with hypertension. Translation of our findings into practice will be enhanced by the pragmatic design of each intervention.

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Table 1**Schedule of Interventions**

Encounter	Module	Definition
1 st & 7 th	Opening [*] Medication Module [*] Literacy	Describe purpose of call, review study Review blood pressure medication prescribed, ascertain if taking as prescribed encouraging individuals to contact providers if change in meds, include family member/friend in description of blood pressure medication purpose, information tailored based upon literacy level and specific to blood pressure meds patients are currently taking, send a chart that outlines blood pressure med schedule, suggest questions to ask primary care provider
	Side Effects [*]	Determine side effects experienced & seriousness and discuss
	Memory ^{**}	Offer mnemonic strategies, explain the importance of taking blood pressure medication consistently
	Closing [*]	Encourage patient to take blood pressure between primary care provider visits.
2 nd & 8 th	Medication Module Literacy	Activated at each call. At any call, nurse reviews if patient doesn't understand what med does, reviews medication changes.
	Hypertension Knowledge ^{**}	Educate & address applicable risk factors: diabetes, race, heredity, new diagnosis
	Decision making ^{**}	Role play to help patient interact with provider more effectively
	Side effects, Closing	
3 rd & 9 th	Diet ^{***}	Review DASH, sodium, and label reading
	Weight ^{**}	Discuss relationship of weight with hypertension and how to reduce weight
	Medication Module literacy, side effects, Closing	
4 th & 10 th	Exercise ^{**}	Provide information based upon stage of change
	Memory	
	Social and medical barriers	Ascertain social support, determine if patient needs referrals, help with refills and provide information about support groups and local resources
	Medication Module Literacy, side effects, closing	
5 th & 11 th	Stress ^{**}	Discuss methods for identifying and reducing stress
	Alcohol ^{**}	Provide information on the relationship between alcohol use and hypertension. Resources are provided
	Medication Module Literacy, side effects, closing	
6 th & 12 th	Medication Module Literacy, side effects, memory, closing	
Any month	Patient Initiated	Address patient concern at time of patient initiated call to nurse

Note

*
=modules activated at every phone call for only those identified as having a problem**
=modules activated at specific intervals for only those identified as having a problem***
=modules activated at specific intervals for all individuals

Table 2

TCYB Baseline Sample Characteristics

Characteristic	Intervention (n=319) percent	Control (n=317)
Male	35%	33%
Married	49%	51%
Live alone	25%	26%
Caucasian	50%	47%
African American	47%	51%
12th grade or less	35%	38%
Functionally illiterate (REALM≤60)	27%	27%
Employed	42%	37%
Inadequate income	18%	21%
Taking blood pressure meds for >5 years.	62%	57%
Parent or sibling with hypertension	78%	76%
No weekly exercise	21%	25%
Ever smoke	54%	62%
Diabetic	34%	38%
Mean Age (SD)	61 years (12.7)	62 years (11.9)