The Cardiovascular Intervention Improvement Telemedicine Study (CITIES): Rationale for a Tailored Behavioral and Educational Pharmacist-Administered Intervention for Achieving Cardiovascular Disease Risk Reduction

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Abstract

Background: *Hypertension, hyperlipidemia, and diabetes are significant, but often preventable, contributors to cardiovascular disease (CVD) risk. Medication and behavioral nonadherence are significant barriers to successful hypertension, hyperlidemia, and diabetes management. Our objective was to describe the theoretical framework underlying a tailored behavioral and educational pharmacist-administered intervention for achieving CVD risk reduction.* ***Materials and Methods:*** *Adults with poorly controlled hypertension and/or hyperlipidemia were enrolled from three outpatient primary care clinics associated with the Durham Veterans Affairs Medical Center (Durham, NC). Participants were randomly assigned to receive a pharmacist-administered, tailored, 1-year telephone-based intervention or usual care. The goal of the study was to reduce the risk for CVD through a theory-driven intervention to increase medication adherence and improve health behaviors.* ***Results:*** *Enrollment began in November 2011 and is ongoing. The target sample size is 500 patients.* ***Conclusions:*** *The Cardiovascular Intervention Improvement Telemedicine Study (CITIES) intervention has been designed with a strong theoretical underpinning. The theoretical foundation and intervention are designed to encourage patients with multiple comorbidities and poorly controlled CVD risk factors to engage in home-based monitoring and tailored telephone-based interventions. Evidence suggests that clinical pharmacist-administered telephone-based interventions may be efficiently integrated into primary care for patients with poorly controlled CVD risk factors.*

Key words: *cardiology/cardiovascular disease, pharmacy, telemedicine*

Introduction

Cardiovascular disease (CVD) is the leading cause of death for Americans.[1] Hypertension, hyperlipidemia, and diabetes are significant, often preventable contributors to CVD risk. These risk factors are multiplicative; patients can decrease their probability of experiencing CVD by modifying dietary habits, increasing physical activity, and making other lifestyle changes. In addition, many patients with poorly controlled CVD risk factors require pharmacological treatment to manage their condition. In order for pharmacological regimens to be effective, medications must be taken consistently as prescribed. An estimated 20–50% of patients are nonadherent with their CVD medications.[2] Medication and behavioral nonadherence are significant barriers to successful chronic disease management.[3]

There have been many efforts to reduce medication and behavioral nonadherence to promote CVD health. The new paradigm in Veterans Affairs (VA) Medical Centers for engaging patients in primary care is the patient-aligned care team (PACT) or patient-centered medical home.[4,5] The core principles of PACT emphasize personal relationships, team delivery of patient-centered care, coordination across specialties, quality and safety improvements, open access, and value-driven care.[4,5]

Previous studies demonstrate the merits of using telephone-based interventions. Telephone-based care is often more convenient and accessible for patients than in-person care.[6–8] It may also reduce patients' travel cost, prevent clinic no-show appointments, and supplement the need for clinic visits. Therefore, telephone-based care may be critical in supporting the PACT vision of coordination across different settings of care while improving access to care. The professional role of the person making the telephone calls is equally important. Pharmacists and nurses have successfully

administered many previous hypertension interventions.[7–11] Compared with nurses, pharmacists provide the added benefit of medication management. The effectiveness of telephone-based interventions is further increased by incorporating tailored information and feedback.[12–14] The purpose of this article is to describe the underlying theoretical framework of the Cardiovascular Intervention Improvement Telemedicine Study (CITIES) intervention.

Materials and Methods

THEORETICAL FRAMEWORK

A synthesis of the health belief model (HBM), the health decision model (HDM), and the transtheoretical model (TTM) informed the structure for this tailored intervention. The HBM is one of the earliest social cognition models. The concept underlying HBM is that an individual's perceived personal threat and barriers to change, coupled with his or her belief in the benefits and effectiveness of the behavior change, will predict one's likelihood of adopting a desired behavior.[15] The HDM builds on the HBM and incorporates decision analysis, behavioral decision theory, and health beliefs to yield a unified model of health decisions and resultant behavior. HDM focuses on health decisions and combines the influences of health beliefs and modifying factors.[16,17] HDM explains some of the underlying behaviors affecting poor CVD control such as decisions to cease smoking and/or adhere to a diet and exercise regimen. Despite its theoretical value, HDM is not designed to comprehensively include the myriad of patient and clinical factors impacting blood pressure (BP) control.[18] The CITIES theoretical framework incorporates elements of both models, expanding to include patient characteristics like medication-related side effects.

In tandem, the HBM and HDM are informative in ascertaining factors that may explain medication adherence and subsequent BP and cholesterol control. However, we need an additional framework to explain factors that hinder or promote cardiovascular health behaviors. The TTM asserts that behavioral change occurs in a temporally ordered series of stages.[13] An individual is hypothesized to move between stages based on the ratio of pros and cons associated with the behavior, self-efficacy, temptations to relapse, and coping mechanisms used to change the problem behavior.[13] To that end, the TTM describes five stages categorizing an individual's interest and motivation to modify a problem behavior. The first stage, "precontemplation," is the stage when there is an unwillingness to change or there is a lack of problem recognition. Second, "contemplation" involves reflecting on the consequences of action or inaction of the problem behavior. At this stage, participants conceptualize the advantages and disadvantages of, for example, taking daily aspirin for heart attack prevention. Next, the "preparation" stage is when there is a commitment to change in the near future. The "action" stage involves successfully modifying behavior for a period of 1 day to 6 months. Lastly, "maintenance" occurs when an individual has engaged in the new behavior for 6 months or more. Emphasis is placed on lifestyle modification to ensure that behavior change is sustained.[14]

Critical to the CITIES intervention is that it encompasses targeted, tailored information and feedback, which has been demonstrated to be effective for modifying multiple behaviors. The intervention is targeted, for example, in that only participants who are actively smoking are presented with the smoking cessation module. Tailored interventions may have increased impact because they can be designed to target issues of particular relevance to an individual.[19] The CITIES intervention content is tailored based on a participant's level of motivation to change, his or her knowledge and understanding of treatment, and counseling on specific behavioral changes. Modules are triggered based on a patient's responses, such as average weekly exercise. The pharmacist assesses the participant's self-reported stage of change, perceived barriers, and self-efficacy related to a health behavior. During subsequent modules the patient's most recent self-reported stage of change is used to tailor content. For example, during predesignated encounters participants are asked, on average, how many hours they exercise weekly. Patients who exercise less than recommended are asked how interested they are in changing their current activity level. Responses reassess a patient's readiness to change (e.g., not ready to change at this time, thinking about changing my activity level, preparing for changed activity level).

By integrating key components of theoretical models,[13,17,20] the CITIES intervention addresses how (1) to establish healthy goals and gain self-efficacy, (2) to implement healthy behaviors, (3) to monitor performance, and (4) to longitudinally maintain healthy behaviors for CVD control. The intervention involves pharmacist-administered telephone counseling tailored for individuals based on behavioral and clinical needs.[21] Although pharmacists may be more costly than other professional interventionists, pharmacists are experts in drug therapy. In addition, pharmacists are able to immediately respond to changes in home-monitored values by adjusting medications. Despite the initial expense pharmacists may ultimately reduce cost by improving patient adherence, thus decreasing unnecessary healthcare utilization.

INTERVENTION PROCEDURES

The pharmacist contacts the patients in the intervention arm by telephone monthly for 1 year. At each call the pharmacist delivers both tailored and standard information from study modules.[22] This monthly frequency was designed based on several factors, including previous experience,[2,20] clinical response, and response to goal setting. One month allows sufficient elapsed time to note discernible effects from medication changes, while still calling soon enough to mitigate any potential adverse events. Similarly, the order of the modules was clinically derived. For example, we address medication adherence in the first pharmacist intervention module. Therefore, specific barriers to medication adherence may be identified early as a source of poor disease control. In subsequent modules medication adjustments may be made to address barriers that a patient previously reported.

The pharmacist uses plain language and nonmedical terminology[23] and requests that patients confirm their understanding of educational information (e.g., teach back, set goals). To ensure that participants in the intervention arm receive standardized information, the pharmacist uses a computerized database that contains

prescripted content and tailoring algorithms. The database also collects information about the call contents and duration, when the participant needs to be contacted again, and what occurred during previous telephone encounters.

RECRUITMENT AND ENROLLMENT

Recruitment and enrollment procedures have been previously described.[22] In brief, potential CITIES participants are identified through an electronic health record query to locate patients who were enrolled in one of three primary care clinics affiliated with the Durham VA Medical Center (Durham, NC). Eligible participants have active outpatient diagnoses codes for hypertension and/or hyperlipidemia with poor control over the last 12 months and are 40 years or older at the time of enrollment. Exclusion criteria include the following: diagnosis of metastatic cancer, active diagnosis of psychosis or dementia, on dialysis, or high creatinine levels (i.e., ≥ 2.5 mg/dL), having had a stroke or myocardial infarction in the past 3 months, lack of access to a telephone at home, resident in a nursing home or receiving home healthcare, severe hearing or vision impairment, participation in another clinical trial or intervention, or a plan to move their healthcare away from the VA. Patients currently followed up for medication management by a PACT clinical pharmacist specialist are also excluded.

Research assistants collect biometric information (e.g., height, weight, BP) and administer the baseline questionnaire. Participants are then randomized into one of two groups: the educational control group or the pharmacist-intervention group. Randomization is stratified based on three participant characteristics, including gender (e.g., male versus female), smoking status (e.g., current smoker versus nonsmoker), and diabetes status (e.g., diabetic versus not diabetic). Participants in the control group (i.e., usual care) are given educational materials about CVD to review independently. Those in the pharmacist-intervention group are given an intervention handbook and trained on the use of home BP equipment and (if clinically appropriate) the use of a glucometer. Participants are directed to the laboratory for collection of a lipid panel and, if applicable, glycosylated hemoglobin level.

Participants return for two additional in-person visits at 6 months and 12 months after enrolling in the study. There is no physical contact with the pharmacist during these encounters. A research assistant collects biometric data again and re-administers the questionnaire. This procedure allows collection of repeated measures of participants' stage of change, enabling testing of the theoretical components of the intervention.

SAMPLE SIZE CALCULATION AND SAMPLE

The sample size estimate is based on the hypothesis that patients in the intervention group will have a greater reduction in their general CVD risk profile compared with patients in the control group. This hypothesis will be tested using the null hypothesis that there is no between-group difference in risk at two follow-up time points (6 and 12 months). Sample size calculations were therefore performed to evaluate the 2 degrees of freedom omnibus test contrasting the two treatment groups at the two time points. Using preliminary data from the V-STITCH study[6] to estimate quantities needed for the sample size calculation, a mean probability of CVD risk of 40% and a standard deviation of 19.5% in both treatment groups at baseline are anticipated. The correlation between the different time points was assumed to be 0.7. We generated sample size estimates for a differential intervention group improvement of 6% by 12 months. For the example patient, if his or her total cholesterol level improved to 185 mg/dL and systolic BP improved to 148 mm Hg, the CVD risk profile would be 35%, an improvement of 6%. Sample size and power were estimated via methods and software discussed by Rochon.[24] A two-sided type-I error rate of 5% and a power of 80% were applied in all calculations. The largest sample size for the omnibus test arises from the fast initial decrease, so that a minimum of 197 participants per treatment group is required, for a total study size of 394 participants. Assuming that 15% of enrollees drop out before the Month 12 evaluation, we need to recruit $394/0.85 = 464$ participants. A 15% dropout rate is conservative; we typically have observed an approximately 10% dropout rate by 12 months in our prior trials. Rounding this up to protect against deviations from our assumptions, a total of 500 total participants (250 per arm) will be recruited and started on the interventions. Based on prior recruitment experience, this is a feasible goal.

The enrollment period began on November 1, 2011 and is ongoing. The enrollment objective is 500 participants. A visual depiction of the study timeline is presented in *Table 1*. The Durham VA Institutional Review Board approved this study. All participants provided informed consent.

INTERVENTION EDUCATIONAL MODULES

A critical component of the intervention is modifying and sustaining specific health behaviors to decrease CVD risk. Because CVD risk factors are multiplicative, the intervention is designed to target multiple behavioral factors simultaneously, creating a synergistic result that is more effective than focusing on an individual problem behavior. The intervention content is divided into modules, each focusing on a specific element of CVD health and risk reduction, which are combined and personalized to target behaviors relevant to a particular patient (*Table 2*). These modules include medication reconciliation, pill refill, disease knowledge/ risk perception, weight management, diet, exercise, smoking cessation, stress reduction, sleep apnea, insomnia, mental health, and hypoglycemia; these factors are not only important to patients' CVD outcome, but are also topics for targeting and tailoring of intervention materials.[22]

MEDICATION ADHERENCE

During the initial medication adherence module, the pharmacist and participant review all CVD-related medications, discuss the purpose of participants' medications, assess for safety, and go over how the medications should be administered. Medication reconciliation (i.e., knowing what the patient may have been prescribed based on electronic records versus what the patient is actually taking) serves as the cornerstone of this module. At subsequent contacts the

Table 1. Study Timeline

	YEAR 1		YEAR 2		YEAR 3		YEAR 4
Pilot work	X						
Hire and train staff	X	X					
Conduct enrollment		X	X	X			
Intervention follow-up				X	X	X	
Conducting analyses						X	X
Preparing reports and manuscripts						X	X

Each block with an X represents a 6-month time interval. For example, 6 months of pilot work is anticipated, 18 months to conduct enrollment (an average of 6 patients per week), and 18 months of intervention follow-up (12 months per patient).

pharmacist reviews recent medication changes via electronic records with participants for patient understanding. Prior to each encounter, the pharmacist, before making medication adjustments examines both patient-reported and electronic health record data for evidence of barriers to medication adherence. Participants who repeatedly forget to take their medications are provided mnemonic strategies. Memory adherence strategies provided to patients include cueing (e.g., pairing taking medication with an established behavior such as brushing teeth), monitoring (e.g., using a calendar to track medication taking), or utilizing a weekly pill reminder container.

MEDICATION SIDE EFFECTS

The pharmacist queries the patient about specific side effects, such as symptoms of hypotension and muscle pain, which may be common with antihypertensive and cholesterol medications, respectively. The pharmacist provides education regarding signs and symptoms to problematic side effects and encourages participants to maintain adherence with their medication regimen based on a greater benefit versus perceived risk. If a participant experiences a side effect, the pharmacist explores how this might impact his or her medication adherence and considers alternative solutions. In the event of a potentially life-threatening side effect, the pharmacist immediately contacts the provider.

During the baseline assessment participants are asked about barriers to obtaining pill refills. Additionally, the pharmacist asked whether participants are lacking pill refills or have difficulties acquiring their prescriptions. For patients having difficulty, the pharmacist educates participants about multiple methods for obtaining refills through the VA.

KNOWLEDGE/RISK PERCEPTION

At baseline patients randomized to the intervention receive this risk knowledge in two encounters. Encounter 1 includes (1) education on CVD risk factors, both modifiable and nonmodifiable, (2) an explanation of cholesterol and appropriate goals, and (3) the benefits of anitplatelet therapy. During Encounter 2 participants receive additional information on hypertension, risks of uncontrolled hypertension, goals of hypertension therapy, and (if clinically indicated) education on diabetes risks and goals of therapy.

HEALTH BEHAVIORS

The CITIES study informs patients about several cardiovascular health behaviors like weight management, diet, exercise, smoking habits, and stress reduction. Patients are provided the evidence-based recommendations regarding these behaviors and will be advised on how to reduce lifestyle risk factors. There is evidence that a healthcare provider's recommendation is the most likely factor to instigate a change in health behavior.[25] Therefore, only those individuals identified as being overweight (body mass index $>25\,kg/m^2$), who report high levels of stress, or who smoke at the time of contact receive information regarding weight management, stress reduction, and smoking cessation, respectively. The pharmacist uses motivational interviewing techniques, engages S.M.A.R.T. strategies (i.e., specific, measureable, attainable, realistic, timely) for individualized goal setting related to managing cardiovascular-related behaviors, and sets specific action plans that enable participants to progress toward their goals.

WEIGHT MANAGEMENT

Because readiness to change fluctuates over time, the pharmacist asks participants about their state of change regarding weight loss during each in-person interview. With this information, the pharmacist facilitates participants' progression through the stages of change by exploring potential barriers to health habits, using motivational interviewing techniques, and setting exercise goals. For participants with an elevated body mass index (e.g., $\geq 25\,kg/m^2$), the importance of maintaining a healthy weight is stressed regardless of participants' stage of change. The pharmacist also ensures that participants set reasonable weight management goals and reminds them that losing even 10 pounds carries health benefits.

DIET

Dietary recommendations focus on improved cholesterol, BP and glycosylated hemoglobin control. Therefore, the pharmacist explains the Dietary Approaches to Stop Hypertension (DASH) diet, which has been demonstrated to lower BP.[26] In addition to the phone-based counseling, participants are given printed materials that include both textual and pictorial information to reinforce what was discussed.

EXERCISE

Considering participants' current health characteristics and stage of change, the pharmacist provides guidance on the benefits of

Table 2. Intervention Module and Associated Theoretical Constructs

MODULE CONTENT	THEORETICAL CONSTRUCTS	EXAMPLE QUESTIONS	DATA SOURCE
1. Medication reconciliation • Medication indication(s) • Medication(s) safety for improved tolerance • Proper drug administration • Barriers to adherence • Strategies to increase adherence • Medication side effects	Perceived barriers, susceptibility, and benefits (HBM)	"What is the main reason you changed/stopped taking this medication(s) for your high blood pressure?" Responses include: • Because of side effects • My medication schedule is too complicated • Cannot remember to take it • Pill(s) too hard to swallow • Afraid to take medications due to side effects • Did not think it was working • Do not think I need it	Pharmacist intervention
2. Knowledge/risk perception of cardiovascular disease • Patient-perceived risk of heart attack and stroke • Education of modifiable and nonmodifiable risk factors for CVD • Risks of uncontrolled hypertension, cholesterol • Benefits of therapy • Appropriate goal setting to reduce CVD risk factors	Perceived severity and threat (HBM)	"How serious do you think it is to have high blood pressure?" Responses include: • Very serious • Serious • A little serious • Not at all serious • Do not know "If over the next 6 months, you don't change any of your health behaviors related to CVD, what do you think is your chance of having a stroke in the next year?" Responses include: • Very likely • Likely • Not likely • Do not know	Patient interview
3. Health behaviors • Education about weight management, diet, exercise, smoking habits, and stress reduction as appropriate given patients' characteristics • Importance of incorporating these as a lifestyle change	Self-efficacy (HBM)	"On a scale of 1 to 10, with 1 being not at all hard and 10 being extremely hard, please rate how hard it is for you to follow recommendations to improve your cardiovascular health regarding diet?" "On a scale of 1 to 10, with 1 being not at all hard and 10 being extremely hard, please rate how hard it is for you to follow recommendations to improve your cardiovascular health regarding exercise?"	Patient interview
a. Weight management • Importance of maintaining a healthy weight • Setting reasonable weight management goals	Readiness to change (TTM)	"Based on your most recent weight at your doctor's office, you are above what guidelines say is ideal. Lowering your weight can help control your heart risk factors. At this time how ready are you to lose weight?" Responses include: • Not ready to do anything at present • Thinking about losing weight • Preparing to lose weight • Taking action to lose weight	Pharmacist intervention
b. Diet • Assessment of dietary habits (i.e., fruit and vegetable consumption) • Explanation of the DASH diet • Sodium reduction; increase fiber and protein consumption • Understanding nutrition labels and portion control • Opportunity to talk about portion control, healthy carbohydrates, and heart-healthy diet in subsequent encounters	Goal setting (HDM)	"Now that we have talked about the benefits of weight loss, is there a weight loss goal you could set for yourself to achieve in 6 months?" Responses include: • Open ended	Pharmacist intervention

continued→

Table 2. Intervention Module and Associated Theoretical Constructs *continued*

MODULE CONTENT	THEORETICAL CONSTRUCTS	EXAMPLE QUESTIONS	DATA SOURCE
c. Exercise • Benefits of increased physical activity and positive exercise behaviors • Problem-solving regarding functional impairments and other physical activity-limiting barriers • Using motivational interviewing techniques goal setting for exercising goals	Readiness to change (TTM)	"Physical activity lowers your cardiac risk factors, relieves stress, and strengthens your heart, muscles, and bones. If you are trying to lose weight, a combination of physical activity and careful food choices can help you reach your target weight and maintain it. You can start getting these benefits even if you haven't been very active in the past. At this time how interested are you in changing your level of physical activity?" Responses include: • Not ready to do anything at present • Taking action to lose weight • Not ready to change at present • Thinking about changing my activity level • Preparing for changed activity level • Already physically active	Pharmacist intervention
d. Smoking • Benefits of smoking cessation and risks of continued smoking tailored to patient's healthcare status and concerns • Initiating and maintaining smoking cessation goals • Strategies to quit (i.e., local resources smoking cessation clinics) • Prescription for nicotine replacement therapy when clinically indicated	Readiness to change (TTM) Goal setting (HDM)	"How interested are you in quitting smoking or using tobacco products?" Responses include: • Not ready to quit yet • Thinking about quitting • Planning to quit soon • In process of quitting "Now that we have talked about the benefits in stopping smoking or using tobacco products, what goal, would you like to set for yourself to achieve in 6 months?" Responses include: • Open ended	Pharmacist intervention
e. Mental health, sleep, and stress reduction • Screening for depression and posttraumatic stress disorder • Educating about the relationship between elevated levels of stress and CVD symptoms • Stress coping mechanisms (i.e., relaxation, meditation) • Benefits of quality sleep • When clinically indicated referral to appropriate resources	Perceived severity (HBM)	"To what extent do you consider your sleep problem to interfere with your daily functioning (e.g., daytime functioning, ability to function at work/daily chores, concentration, memory, mood, etc.)?" Responses include: • Not at all • A little • Somewhat • Much • Very much • Do not know	Patient interview

The items listed are not exhaustive, but are intended to provide examples of questions that are used to tailor intervention content.

CVD, cardiovascular disease; DASH, Dietary Approaches to Stop Hypertension; HBM, health belief model; HDM, health decision model; TTM, transtheoretical model.

increased physical activity, reinforces positive exercise behaviors, and helps participants problem-solve regarding any functional impairments or other barriers that limit physical activity. The pharmacist uses motivational interviewing principles to help participants set realistic exercise goals.

SMOKING

For participants who smoke at the time of contact, the pharmacist employs motivational interviewing techniques and tailored intervention materials geared toward smoking cessation. Barriers to initiating and maintaining smoking cessation, benefits of quitting, and strategies to quit are discussed. Participants are also referred to local resources including smoking cessation clinics and nicotine replacement therapy. The delivery of nicotine replacement therapy is determined by the number of cigarettes smoked per day.[27] The pharmacist prescribes nicotine replacement therapy based on these principles.

MENTAL HEALTH, SLEEP, AND STRESS REDUCTION

Individuals reporting sleep problems are educated about the relationship between elevated levels of stress and CVD symptoms. The intervention materials address stress coping mechanisms, including relaxation, meditation, referral to a sleep apnea clinic for a mask adjustment (when appropriate), and the benefits of quality sleep.

PATIENT-ACTIVATED ENCOUNTER

Intervention participants are also able to initiate conversations with the study pharmacist. Any emergent health issues that arise are

immediately directed to participants' primary care provider or other provider as appropriate.

INTERVENTION TECHNIQUES

CITIES utilizes two intervention techniques—motivational interviews and home monitoring—to help patients progress through stages of change. Motivational interviewing is a patient-centered communication method designed to explore and resolve ambivalence to health behavior change.[28,29] This technique has been demonstrated effective in promoting healthy behaviors related to a myriad of CVD risk factors. including diabetes,[30–32] and is a patient-driven, comprehensive approach that can address behavioral, medical, and psychosocial issues. Pharmacists are knowledgeable about appropriate health behaviors and typical barriers to adherence. Additionally, contact with the study pharmacist may improve continuity of care and facilitates communication about behavior change between patients and an interdisciplinary care team.

The use of home monitoring of BP and blood glucose is an increasingly common element of primary care. Home monitoring requires minimal participant burden, yet equips participants with the skills and information needed for engagement in their disease management. Home monitoring also provides more frequent measurement readings than collected in a clinic setting, where appointments are often months apart.[33] During monthly phone calls, patients report a continuous stream of readings enabling the pharmacist to respond to participants' home-monitored values in between clinic visits, thus filling an important gap in patient-centered care. In order to inform medication adjustment the pharmacist requires, on average, at least three BP readings weekly. Similarly, patients with diabetes provide blood glucose readings at least once weekly. Patients may report more frequent readings if prescribed multiple daily insulin injections for management of their diabetes.

CONTROL GROUP

Participants randomized to the control group continue to be managed by their primary care provider and usual healthcare team. The control group has no contact with the study pharmacist and is not instructed to monitor BP and/or blood glucose levels at home.

Results

Patient enrollment began on November 1, 2011 and is ongoing. As of April 2013, CITIES had reviewed records and/or contacted 2,906 unique patients associated with the Durham VAMC. Of those patients, 969 (24%) were either ineligible or refused, 356 (12%) have been enrolled, and 1,581 (54%) remain in the enrollment queue. This equates with an enrollment rate of between 30% and 45%.

Discussion

The CITIES intervention is a theory-driven, pharmacist-administered, telephone intervention. The theoretical models supporting the intervention inform both the structure and flow of the modules. Home-based monitoring and telephone-based care can alleviate strain on both patients and the healthcare system by increasing efficiency and communication between patient and provider. Home-based care encourages patients to become more actively engaged in managing their health. This is critical because over half of patients cease taking their antihypertensive and other CVD-related drugs within their first year of treatment.[34–36] Adherent patients have better health outcomes than nonadherent patients, even when taking a placebo.[37] By equipping patients with educational and behavioral tools at home, we may help them reduce their CVD risk.

We use a pharmacist interventionist. Pharmacists are skilled in counseling patients about health benefits of making lifestyle changes, motivating patients through stages of change and proper medication administration, and in providing strategies to increase medication adherence. Pharmacists also facilitate quality communication between patient and primary care provider by helping patients understand how they can engage in self-management and when physician involvement is needed. Providing care over the telephone reduces cost both to the patient in terms of travel and time burden and to the healthcare system in terms of opening clinic appointments for patients with complex or acute health needs.

Despite these advantages, limitations must be addressed. With increasing technology, there are a myriad of mechanisms for intervention administration. Some of these include remotely monitoring pillbox openings, transferring self-monitored data remotely, and text-messaging patients with medication changes. The effectiveness of these high-resource technologies has, in most cases, not necessarily been tested. The relatively low-technology design of CITIES was carefully chosen because of the potential for broad dissemination without a substantial increase in required resources. Participants in the intervention group are provided with home monitoring equipment and are trained in its proper utilization. However, it is possible that participants may either incorrectly measure their BP or inaccurately report it. Moreover, to assess adherence we used a valid, reliable measure,[38] but there are potential issues with participants underreporting their nonadherence. We chose to rely on self-reported data because, given the VA's emphasis on patient-centered care, a focus on self-reported measures was appropriate.

The CITIES intervention is designed to increase adherence and build participant engagement in self-monitoring and management of hypertension and other CVD risk factors. By working on multiple risk factors in unison, we anticipate progression through stages of changed resulting in improvements in self-reported medication adherence and clinical values. The study includes common educational models, as well as tailored participant-specific information based on the baseline interview assessment. This results in variable time required for the monthly intervention telephone calls. Given the increasing population of older adults, complexity of managing patients with multiple chronic conditions, and resulting increasing burden on primary care teams, interventions demonstrating improvements across multiple behaviors while training patients to manage their own health are an efficient, effective method for both healthcare cost reduction and improved care quality.

Many adults with multiple CVD risk factors continue to be nonadherent with their medication and health behaviors, despite clinicians' guidance. The goal of the CITIES intervention is to maintain disease control, increase medication adherence, and improve health behaviors for CVD risk reduction. Translation of these findings into clinical practice will be enhanced by the practical design and reproducibility of the intervention.

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No competing financial interests exist.

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