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A Multifaceted Prospective Memory Intervention to Improve Medication Adherence: Design of a Randomized Control Trial

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Abstract

Adherence to prescribed antihypertensive agents is critical because control of elevated blood pressure is the single most important way to prevent stroke and other end organ damage. Unfortunately, nonadherence remains a significant problem. Previous interventions designed to improve adherence have demonstrated only small benefits of strategies that target single facets such as understanding medication directions. The intervention described here is informed by prospective memory theory and performance of older adults in laboratory-based paradigms and uses a comprehensive, multifaceted approach to improve adherence. It incorporates multiple strategies designed to support key components of prospective remembering involved in taking medication. The intervention is delivered by nurses in the home with an education control group for comparison. Differences between groups in overall adherence following the intervention and 6 months later will be tested. Systolic and diastolic blood pressure levels also will be examined between groups and as it relates to adherence. Intra-individual regression is planned to examine change in adherence over time and its predictors. Finally, we will examine the association between executive function/working memory and adherence, predicting that adherence will be related to executive/working memory in the control group but not in the intervention group.

Keywords

prospective memory; medication adherence; self-management; cognition; intervention; hypertension

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Introduction

Fifty percent of older adults do not adhere to antihypertensive agents. Nonadherence is associated with increased risk of major cardiovascular events and death [1] and is the single most modifiable risk reduction factor for stroke [2]. The need to control hypertension is clear and the problem is significant in numbers alone because 60 – 80% of older adults have hypertension [3]. Unfortunately, people do not fully adhere to medication regimens despite extensive interventions to educate, motivate, and support adherence behaviors [for reviews see 4, 5–8].

There is good evidence associating cognitive function and medication adherence [9, 10, for a review see 11]. According to Stone, the most common reasons for non-adherence are forgetfulness, changing medication schedules or busy lifestyles. Each of these reasons is potentially cognitive in nature. Specifically, forgetfulness is failing to remember to take medications at the designated times, changing schedules is likely to interfere with memory strategies that are based on routine and on associated environmental cues in one's routine context, and busy lifestyles contribute to nonadherence by adding cognitive distraction that challenge limited working memory capacity. Adherence may especially depend on executive function and working memory [9] because past research demonstrates only small effects of interventions that address education [e.g. 12] or the design of medication instructions (and therefore patient understanding) [see for example 13]. Therefore, adherence may be improved by interventions that target executive function and working memory.

Assuming good motivation to faithfully follow one's medication regimen, successful adherence to a medication schedule requires a complex set of cognitive processes. Over the past 20–25 years, there has been rapid growth in research on prospective memory resulting in better understanding of the component processes involved in remembering to perform actions in the future [14, 15]. Specifically, successful prospective remembering involves good encoding of the task demands, retaining these demands in memory, and retrieving them at the appropriate moment in time. It also involves initiating the execution of the action, often in the face of distraction, and then monitoring one's action so that a dose is not mistakenly repeated. Given that successful medication adherence involves many processes and that each is vulnerable to failure, it is not surprising that adherence is often less than optimal and that proper adherence is related to levels of cognitive functioning [10, 16].

As we age, we are much more likely to develop chronic conditions that are treated with medications and yet we also experience changes in cognitive functioning that can undermine successful adherence to prescribed medication regimens. Research on aging and memory shows that aging causes general declines on a variety of cognitive functions, including processing speed, attention, working memory capacity, the ability to learn new information, and the ability to retrieve information [17–19]. These age related cognitive declines are robust [e.g., 20, 21]. Given the multiple cognitive processes described above that are involved in remembering to follow a medication regimen, it is not surprising that compromised cognitive functioning significantly impairs medication adherence [10]. The purpose of this article is to describe an in-home, tailored, multifaceted intervention that

specifically targets remembering strategies for improving adherence to antihypertensive medication.

Overview of the Intervention

There are two results in the prospective memory and aging literatures that suggest that an intervention strategy that targets memory processes will be successful. One is that there is remarkable variability in age effects on laboratory tests of prospective memory, with some studies showing minimal or no age differences [22–25] and others showing striking age differences [e.g., 26, 27, 28]. Another is that there is evidence that aging has more pronounced disruptive effects on cognitive functioning mediated by the frontal lobes (e.g., working memory and executive attention [29–31] than on cognitive functioning mediated by the medial temporal areas (e.g., relatively automatic associative retrieval processes). Consistent with recent reviews of the aging and prospective memory literature [18, 25, 31], the emerging pattern is that older adults show substantial deficits when they rely on working memory and executive resources for prospective remembering but minimal deficits when they rely on mostly preserved and relatively automatic associative retrieval processes. For example, age differences are robust on prospective memory tasks that require strategic monitoring for the correct opportunity for performing an intended action or when the retrieved action must be delayed (thus placing a demand on working memory and attentional resources for keeping the retrieved intention activated over the delay). In contrast, age differences are minimal when there are good external or environmental cues that support relatively automatic retrieval of the intended action (cues that have been associated with intended actions) and when the action can be performed immediately. Thus, the general focus of our intervention is to encourage older adults' use of environmentally supported associative retrieval processes (thought to be relatively spared with age) in place of prospective memory processes that heavily rely on working memory and executive resources (thought to be compromised with age).

The intervention targets all of the memory and attentional processes thought to be critical for successful prospective memory performance in everyday tasks such as medication taking [15, 32]. These include (1) forming a good encoding of the intended action and the condition(s) that is appropriate for initiating the action, (2) remembering the intention over the retention interval, (3) retrieving the intention at the appropriate point in time, (4) inhibiting other ongoing activities at the critical time and actually executing the action, and (5) monitoring performance of the action so that the person remembers performing it (and therefore does not repeat it). Failure at any one of these tasks could compromise medication adherence. For example, a person may form only a general intention to take her or his medicine in the morning and may fail to think of it at the appropriate time. Or, that person may retrieve the intention to take the medication at the right time but because of distractions or interruptions at that time may fail to follow through and execute the action. Or, after establishing a routine, the person may automatically take a dose while deeply engaged in other thoughts and a few minutes later forget that he or she had already taken the medication and take it again resulting in taking too much medication. Consequently, the intervention directly targets each of these tasks.

The following general principles guided the development of the intervention. First, we used techniques that have been empirically demonstrated to improve medication adherence and/or prospective memory and to be effective with older adults. Second, consistent with the view outlined above that medication adherence is a complex process [8], we developed a comprehensive approach to adherence. Specifically, we developed a multifaceted intervention that targets all of the cognitive processes thought to be involved in remembering to take medication. As illustrated above, the idea is that problems in any one component process can undermine successful performance and thus it is critical to support all of the component processes. Third, because successful performance of any one process is probabilistic in nature, the intervention included redundancy so that there were backup routes for accomplishing each process. The intervention especially focuses on retrieval of the intention, which according to some researchers is particularly vulnerable in older adults [27], and each process of prospective remembering (encoding, retention, retrieval, execution, and monitoring) is targeted by at least two strategies in the intervention. Fourth, as developed earlier, the intervention capitalizes on abilities that are relatively preserved with age and reduces reliance on age-vulnerable abilities. In particular, it relies extensively on relatively well-preserved associative processes that respond more or less automatically to stimuli that have been associated with the intention (e.g., on cuing from environmental stimuli), while reducing reliance on working memory and executive function (e.g., self-initiated monitoring), which prior research has shown are susceptible to the effects of aging [30, 33]. Consistent with this, Henry and colleagues' [34] meta-analysis showed significantly smaller effects of age on prospective memory tasks supported by relatively automatic processes, $r = -.14$, compared to prospective memory tasks demanding active monitoring processes, $r = -.40$; [18, 25, 31]. For example, if people think that they should take their medication at 8:00 am, then they need to actively monitor the clock in order to determine whether the time is appropriate for taking their pill. According to current cognitive theories, actively monitoring the clock and inhibiting ongoing activities in order to actually check the clock require extensive working memory and executive resources [35, 36]. By getting people to reinterpret their task as one of taking medication with breakfast and then getting them to create an associative link between the external signal of breakfast (the cue or stimulus) and taking medication (the intended action), it is likely that the occurrence of breakfast will trigger retrieval of the intended action [see 37]. Thus, through this simple reinterpretation of the task, prospective memory retrieval is accomplished through associative processes that are thought to be spared with age as opposed to working memory and executive processes that have been shown to decline with age.

Our final principle in designing our intervention was based on Bargh and Chartrand's [38] theory that humans have a limited capacity for conscious control over behavior, that conscious self-regulation is a limited capacity that is quickly depleted [39], and that many, if not most, of our behaviors are unconsciously initiated by stimuli in our environment. For example Holland, Hendriks and Aarts have shown that introducing the weak scent of a citrus cleaner into a room leads subjects to unconsciously engage in more cleaning behaviors [40]. Translated into a medication adherence intervention, this means that the average person is unlikely to consistently use cumbersome capacity-consuming processes like monitoring. Evidence indicates that even memory psychologists rarely use burdensome mnemonic

devices in retrospective memory situations, despite their clearly demonstrated effectiveness [41]. Thus, whenever possible, the fifth principle was to reduce reliance on consciously demanding processes. As examples, we encouraged intervention participants to use relatively automatic processes that are set in motion in response to stimuli and also to perform an intended action as soon as they thought about it (thereby obviating the need to use executive and working memory resources to monitor for critical events over delays).

The strategies to be implemented, as well as the processes that they were designed to affect, are outlined in Table 1. We ask participants to link medication taking to their daily routines and we work with them to do this. Emphasizing routine and linking medication taking to this routine facilitates prospective retrieval because the routine promotes the association of medication taking with existing patterns and bypasses the more vulnerable cognitive processes of executive function and working memory. We work with participants to help them identify good cues within their daily practices in their homes that function as triggers for performing the intended action. A good cue is one that is easily noticed and will trigger the retrieval of the intention to take medications, for example, linking medication taking with brushing teeth or eating a meal. Medication taking can also be linked to visual reminders. Placing the medicines in an area where they will be visible, for example, in the center of the breakfast table rather than in a drawer, is also a cue.

We ask participants to use events rather than time as a cue or trigger to take the medication as intended. Changing a time-based task (take medication at 7:00 a.m.), to an event based task (take medication when you set the breakfast plate on the table, or make coffee, or turn on a particular television program) provides associative cues and facilitates retrieval [35].

We ask participants to elaborate the action of taking medicines to make the event more salient and distinct, so that they are more likely to remember having taken it [42]. We explain that doing something to make the action of taking the medicine more memorable, for example, shaking the bottle of pills before taking the pill, will prevent the repetition of a dose. One concern about having a routine is that it may make the monitoring of the completion of an activity more difficult. As the event becomes routine it can also become less salient which can lead to confusion such as the following: “did I take the medicine or do I just think I took it because I’ve been taking the same medication every day for the past two years?” Shaking the bottle makes the event more complex, involves more conscious awareness and creates more cues for monitoring whether the medication was taken as intended.

We also encourage participants to “Do it now” because even a short delay, as brief as 5 seconds, can cause forgetting to take the medication as intended [43]. This strategy is important for supporting execution of the intended action.

We ask participants to use the provided organizer to facilitate monitoring of whether the medication was taken as intended. We give participants a box with 7 sections. Each section labeled with the first letter of each day of the week that accommodates the Medication Electronic Monitoring System (MEMS) cap. We give one to everyone who was using a medication organizer prior to the study and to everyone in the intervention group. We

provide two boxes: one labeled A.M. and one P.M. in the event the monitored medication is to be taken twice a day. After taking their medications, we ask participants to move the MEMS bottle to the next slot in order to help them remember that they have already taken their medication at the current time.

Prospective memory is also supported by having participants create implementation intentions, which involve imagining exactly when and where they will perform an intended action. The principle is “when X arises, I’m going to perform Y” and it needs to be tailored so that the participant can imagine doing it in the context of their daily routine [37, 44]. For example, instead of forming the general intention to take medication in the morning, participants might be encouraged to form the implementation, “When I have my orange juice with breakfast in the morning, I will take my medications.” As part of the intervention, we also encourage participants to imagine performing the action in that particular context, and we walk through (rehearse) the planned medication taking event with the participant in that context.

We also use spaced retrieval, (teach, ask, wait, ask again, wait ask again) in order to support encoding, retention, and retrieval processes involved in medication taking. We ask participant to recall the information we have just presented. Then we wait one minute and ask participant to recall the information again and importantly how they are going to enact the medication taking event, e.g. where, when, how and imagine doing it. Then we ask again in 15 minutes. When the session ends, we ask participants once more to recall the information. The benefit of having the participants actively retrieve the intention is that research has shown that spaced retrieval improves memory for the intention [45].

Finally, we ask participants to practice with us in their home setting. For example, we have participants practice walking to the kitchen to fill the orange juice glass and take the medication. This final step helps participants consolidate their strategies and provides another opportunity to address any remaining questions.

The Education Control Condition

We are using an education comparison group to control for the possible benefit of developing a relationship with a health care provider and education on adherence. Using the education comparison as the control group acknowledges evidence of the value of relationships with health care providers to improve adherence [46, 47] and the role of education to improve adherence (the necessary components of encoding and retention are involved in the education portion of the intervention), although education-only interventions provide only small effects [for a review of medication adherence interventions see 8, 48]. Nurses assigned to each group are trained in the principles of developing a relationship and encouraged to establish rapport with participants. Participants in both groups receive education on hypertension and antihypertensives. The education portion was developed from internet materials from the American Heart Association and the National Heart Lung and Blood Institute [49, 50] that were designed for the general public and addressed issues of hypertension and types of antihypertensives. Both groups are given information on the importance of controlling high blood pressure to prevent stroke and other end organ damage.

Nurses for each group are in the home the same amount of time. Once the education comparison group receives education, the nurse assigned to this group discusses prevention of falls (for example, the benefit of eliminating scatter rugs, use of hand rails on stairs) and engages in social interaction. Therefore, the only difference between the two groups is the use of the prospective memory strategies in the intervention group. Using the education control comparison group provides a strong test of the effectiveness of the prospective memory intervention.

Research Design and Methods

The main hypothesis to be tested in this intervention study is whether individuals in the multifaceted prospective memory intervention group are more adherent to antihypertensive medications than those in the education comparison group both immediately following the intervention and over the six months of testing. By targeting memory and attentional processes, we anticipate that the intervention will improve self-management of medications. Moreover, because the intervention is designed to reduce reliance on executive and working memory resources and to increase reliance on associative processes spared by aging, we further hypothesize that individual differences in working memory capacity will be associated with medication adherence in the control condition, but not in the intervention condition.

Sample

Participants are older community-dwelling adults (≥ 65 years of age) who self-manage at least one prescribed antihypertensive agent. We exclude the following individuals: 1) those residing in nursing homes or receiving home assistance because they are unlikely to self-manage their medications; 2) those who have severe depression (score greater than 11 on the short form of the Geriatric Depression Scale) [51] because severe depression can influence cognition [52, 53]; 3) those with signs of dementia (score below 24 on the MMSE) [54] because pilot study suggests that participants who score low on the MMSE do not benefit from the intervention [55]; and 4) those who are non-English speakers because the cognitive measures are norm-referenced only for English speakers. English speaking is defined as self-reported ability to speak, read and understand English.

Recruitment involves making contacts with several community based senior meal programs, education programs and health fairs where study staff provide blood pressure screenings for older adults. The composition of the sample is likely to be predominantly women (inclusion criteria ≥ 65 years) and predominantly white consistent with the local community. If participants are interested in possible involvement in the study, they are given more information and a follow up phone call to schedule an appointment. At this time we mail a consent form, map, and appointment confirmation. If the potential participant is uncomfortable or unable to drive to the University, we provide cab service and wait for the cab in front of the building.

We believe it is best to provide a consent form to potential participants prior to the initial meeting so that they can be fully informed by reading the consent form, possibly with the help of family or others. The consent form is then read again to the participant at the first

meeting prior to data collection as the participant reads along. Using this method helps ensure that participants understand the purposes of the study, length of time involved and the type of measures that will be obtained. Although we do not specifically tell participants that we are examining adherence using an electronic monitoring system, we do indicate that we are counting their medications and that it will be necessary for the participant to use the container with the special cap. Participants are compensated for the initial 4 weeks of baseline testing and adherence monitoring. Those who are enrolled for the 6 month intervention phase receive additional compensation.

Participants are initially monitored for adherence over four-weeks in order to screen out those who do not have adherence problems. Specifically, we include individuals whose adherence is less than or equal to 90% of the inter-dose interval over this four-week medication monitoring period. Adherence to the inter-dose interval requires taking the medication within 25% of the between dose interval prior to or following the scheduled time to take the medication. We use 90% or lower adherence over the 4 weeks of baseline monitoring as an inclusion criterion because other studies have found that using the medication electronic monitoring system introduces some novelty that can initially boost adherence [56, 57] suggesting usual adherence if not using this new white cap, the MEMS cap, is likely to be less than 90% over the first 4 weeks. Additionally, in other work, it has been demonstrated that an 88% cut point for cardiovascular drugs was needed to improve clinical outcomes in certain cases [58]. We are using the MEMS [59] to measure adherence because when compared with other methods with the exception of blood levels of active metabolites of the ingested drugs, it is the most valid indicator of adherence [60].

Using an electronic monitoring device is not without threats to validity. Some participants (now at 30 out of the 275), were re-monitored for the 4-weeks of baseline adherence because these participants indicated they had not used the MEMS cap as instructed. We use “a teach-teach back” approach to the instructions to help ensure the participants understand the instructions and retain this information over the course of the baseline 4-weeks monitoring period [61]. Nonetheless, certain individuals either did not understand the instructions or retain this information over the course of the baseline 4 week monitoring period. We will examine this subgroup when performing the final analyses.

If participants are prescribed more than one antihypertensive agent, the choice of which medication to monitor is determined randomly. If the participant is taking a diuretic in addition to other antihypertensive agents, we did not include the diuretic because individuals are known to withhold diuretics if they will be out of the home for the day to prevent unwanted trips to the bathroom [62]. However, all other antihypertensive agents are written on a piece of paper and placed in an opaque envelope. The research assistant then withdraws one slip of paper and this determines the antihypertensive agent which will be monitored.

A power analysis was conducted to determine the final sample size. A meaningful (i.e. clinically significant) difference between the two groups was determined to be 18 percentage points. Participants in a prior study had a mean adherence of 62% of days. Acceptable standards of adherence were set at 80%, although this “ballpark” figure is often criticized because acceptable adherence is a function of both the medication and the clinical

response to the medication [63]. For the purpose of calculating the sample size, using an 18% difference (80%-62%), a standard deviation of 28 from the same preliminary study, a one-tailed alpha of .05, and a power of .90, it was determined that a final sample size of 43 per group, or a total sample size of 86 was needed.

To allow for up to a 15% attrition rate, the sample size was increased to 102. Anticipating that approximately 50% of those screened over the first 4 weeks would be eligible for the study, 204 individuals were needed for 4 weeks of baseline monitoring with roughly one half of these participants then randomly assigned to one of the two groups.

Following the 4 weeks of baseline adherence monitoring, eligible participants are randomly assigned to either the multifaceted prospective memory intervention or the education comparison group using a block procedure to enhance the likelihood of obtaining equal groups. That is, two identical slips of paper were placed in an opaque envelope. On one slip of paper the intervention group was written, on another the control group. Following standard procedures, the first member of a group of two is assigned to the intervention or the control group, the second member of a group of two is assigned to the alternative group.

Procedure

The study consists of the following phases: 1) initial visit for baseline data collection; 2) measurement of baseline adherence over 4 weeks; 3) random assignment of eligible participants to the education comparison group or the intervention group; 4) four weekly in-home nurse visits to deliver the education control or intervention; 5) adherence monitoring and outcome measures (over a 6 month period).

For the baseline visit, participants are asked to bring their blood pressure medicines and a list of all their medications. Baseline data collection is conducted at the university with exceptions made thus far for 31 home-bound participants or who lived in an adjacent community where the drive to the university is viewed as burdensome. The initial data collection lasts approximately two hours and consists of obtaining informed consent, gathering information on participant demographics, completing cognitive assessments and questionnaires (discussed in a later section), and transferring one prescribed antihypertensive medication into an electronic medication monitoring bottle.

After randomly assigning participants to one of the two conditions, the nurses conduct four weekly in-home visits. Different nurses deliver the intervention or the education comparison. At the follow up weekly visits, the nurses assigned to the intervention review the recommended strategies. During the intervention nurse visits, difficulties implementing the strategies are explored and strategies for overcoming the difficulties are developed.

The intervention nurse's interactions are voice recorded to track both fidelity to the intervention protocol and to identify how the strategies are tailored to participants' individual schedule and needs. Drift from the intervention protocol is examined by reviewing the voice record to identify areas in which the intervention strayed from the protocol with the goal of re-establishing the protocol. When there is drift (e.g., the intervener did not respond to opportunities to implement the strategies, or diverted attention away from

the strategies), the project coordinator discusses these with the intervention nurse in order to provide guidance in maintaining fidelity to the intervention protocol. Fidelity in the education control group is also monitored by a voice recorder and follows the same procedures for monitoring fidelity.

To prevent loss of data over the 5 months of ongoing monitoring following the end of the one –month intervention phase, a research assistant visits the home every two months to download the data from the MEMS cap. The need to protect against loss of data is balanced with acknowledgement that this is a study examining the strength of a prospective memory intervention to improve adherence. Research assistants who make the visits can be viewed as a memory cue, that is, as a reminder to take the medications. The research assistants making the visits are careful not to discuss the intervention in each condition.

Blood pressure, both seated and standing, are taken twice during each meeting with participants. The seated measures are averaged and the standing measures are averaged for both systolic and diastolic pressures. It is possible that strategies that improve medication adherence could result in lowered blood pressure as some participants may not have been adherent prior to their participation in this study. Therefore along with checking for orthostatic changes in blood pressure, participants are instructed to tell us if they experience or have experienced dizziness, light-headedness, or fainting. If participants have elevated blood pressure (greater than 180 mm Hg systolic or 120 mm Hg diastolic), they are referred to their health care provider and in some situations, the primary care provider or cardiologist can be called to notify them of the elevation. Thus far, 2 participants were taken to the emergency department upon the instructions of the primary care provider during baseline data collection.

Measures

Measures of participant demographic, health and cognition are collected during the baseline visit. Measures of beliefs and values of the medication are taken at the 4 week baseline adherence monitoring visit and the final 6 month visit. The Mini-Mental Status Exam (MMSE) is obtained at the baseline visit and again at the 6 month end visit.

Demographic variables—Demographic variables are collected using a screening and demographics form created for this study that contains questions about age, educational level, and perceived severity of hypertension (length of time diagnosed with hypertension, if the hypertension has been controlled, and if so for how long). Items about severity of hypertension will be examined between groups to gauge the equivalence of the groups and to describe the sample. The demographics form includes a list of medications that the person is currently taking and the schedules for these medications. Regimen complexity is measured as the number of times a day that the monitored medication is prescribed and is included because complexity is often associated with adherence [64]. The overall number of medications, both prescribed and over the counter, is noted and will be used in later analyses to examine associations with regimen complexity.

Health Status—The Older Americans Resources and Services (PHI, OARS-OMFAQ) subscale is used to count the number of chronic illnesses, the subjective assessments of

current health status and the impact of the illness on quality of life [65]. The PHI subscale of the OARS has been modified to eliminate the medication list. Comorbidity is indexed by the sum of items 1–5 and items 8–19 on the severity of illness section of the health impairment subscale (PHI).

Cognitive function—Several cognitive assessments are obtained at baseline. Working memory is measured with operation span [66]. The Operation Span Task is a standard measure of working memory capacity that is used extensively with older adults [66, 67]. The test requires participants to read a simple math equation, determine if the given answer is correct, and then read a target word. After several trials, the person is asked to recall all of the target words [67, 68]. Performance on this working memory task correlates highly with performance on a variety of cognitive tasks, including reading and listening comprehension, vocabulary learning, note taking, writing ability, reasoning, and complex learning [67]. Engle and Kane and their colleagues [67, 68] theorized that the underlying factor in performance on the operation span task is a domain general executive attention function that serves to maintain information in an active and accessible state, particularly in the presence of interference or distraction.

Executive function is measured using the number of perseverative responses and categories achieved on the 64 computer card sorting version of the Wisconsin Card Sorting Test (WCST) [69]. The WCST uses 4 cards with 4 colors and 4 shapes. Individuals must determine the sorting rule. After 10 consecutive correct responses, the sorting rule changes. Individuals who are able to discard the original sorting rule in favor of a new strategy have fewer perseverative errors and achieve more categories.

Additional cognitive factors—Additional cognitive variables that may be associated with medication adherence are included and will be examined. General memory ability, that is, the ability to recall and recognize cues, is assessed with Logical Memory, a subtest from the Wechsler Memory Scale III [70, 71].

Functional health literacy, or the ability to find, understand, and make decisions about information needed for health care decisions, is included because health literacy measures are found to predict health outcomes among older adults with chronic illness [72]. Health literacy is being measured with the Short Form of the Test of Functional Health Literacy in Adults (S-TOFHLA) [73].

The Shipley Vocabulary Test [74] is used at baseline to assess crystallized intelligence. The Brief Illness Perception Questionnaire [75] is used to assess illness representation and the Values and Beliefs Questionnaire (developed for this study) is used to assess participant reported belief in the medication and whether or not the medication was taken as intended. Participants assigned to the intervention group will again be asked about the strategies they used and if the strategies were helpful at the end of the 6 month ongoing monitoring period.

Results

We are 3 ½ years into this 4 year study and have recruited 275 participants, a larger number than originally planned to increase the power to detect a smaller effect size than the

moderate effect used in our initial calculations. Eligibility, that is, adherence to the prescribed medication less than 90% was found for one half of our sample. Our recruitment efforts have been successful and are explained in detail elsewhere [see 76].

Planned analyses—Planned analyses include comparing groups on measures of adherence and systolic and diastolic blood pressure after the intervention and again at 6 months. Preliminary analyses will assess whether baseline measures should be included as covariates and subsequently ANOVAs or ANCOVAs will be used to test for differences between the intervention and education control groups. Regression analysis will be used to predict blood pressure from adherence. We also plan intra-individual regressions to obtain the rate of change in adherence. We will regress the slopes obtained in the intra-individual regression on variables like age, memory function, education and depression to determine if individual factors are associated with change in adherence. To test the hypothesis that working memory and adherence will be related to adherence in the control group, but not in the intervention group, adherence will be regressed on working memory, the group variable (intervention = 1, control = 0), and the working memory by group product term. A significant working memory by group product term (i.e. a significant interaction) will indicate that the relationship between adherence and working memory differs between the intervention group and the control group.

Discussion

Self-management and specifically adhering to antihypertensive medications remains an important concern because adherence tends to be low for this asymptomatic disease, and uncontrolled or undercontrolled hypertension is associated with poor health outcomes including white matter hyperintensities and stroke [77, 78]. Based on research and theories in the areas of prospective memory and aging, the key and novel features of this described intervention are that it addressed all components of prospective remembering in multiple ways and in an integrated and comprehensive fashion. It also focused on strategies that rely on processes that are relatively well preserved in older adults. The intervention has the potential to address the significant problem of nonadherence to prescribed medication with the goal of improving health outcomes among older adults.

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Table 1

Cognitive Intervention Protocol and Component Strategies

Intervention Strategies	Processes Critical for Successful Prospective Memory				
	Encoding	Retention	Retrieval	Retrieval	Monitoring
A. Emphasize routine (same place, same medications)			X		
B. Develop cues			X	X	X
C. Convert time-based to event-based			X		
D. Elaborate the action of taking medicines.					X
E. Do it now				X	
F. Use an Organizer				X	X
G. Use Implementation Intentions	X	X	X		
H. Spaced Retrieval (teach-wait-ask, ask again)	X	X	X		
I. Practice	X	X	X		