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Reducing Adverse Self-Medication Behaviors in Older Adults with Hypertension: Results of an *e*-health Clinical Efficacy Trial

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Abstract A randomized controlled efficacy trial targeting older adults with hypertension (age 60 and over) provided an *e*-health, tailored intervention with the "next generation" of the Personal Education Program (PEP-NG). Eleven primary care practices with advanced practice registered nurse (APRN) providers participated. Participants (N=160) were randomly assigned by the PEP-NG (accessed via a wireless touchscreen tablet computer) to either control (entailing data collection and four routine APRN visits) or tailored intervention (involving PEP-NG intervention and four focused APRN visits) group. Compared to patients in the control group, patients receiving the PEP-NG *e*-health intervention achieved significant increases in both self-medication knowledge and self-efficacy measures, with large effect sizes. Among patients not at BP targets upon entry to the study, therapy intensification in controls

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(increased antihypertensive dose and/or an additional antihypertensive) was significant (p=.001) with an odds ratio of 21.27 in the control compared to the intervention group. Among patients not at BP targets on visit 1, there was a significant declining linear trend in proportion of the intervention group taking NSAIDs 21–31 days/month (p=0.008). Satisfaction with the PEP-NG and the APRN provider relationship was high in both groups. These results suggest that the PEP-NG *e*-health intervention in primary care practices is effective in increasing knowledge and self-efficacy, as well as improving behavior regarding adverse self-medication practices among older adults with hypertension.

Keywords Hypertension · Self-medication management · Older adults · Tailored intervention · *e*-health

Objectives

According to the World Health Organization, hypertension represents the greatest risk factor for premature death worldwide (Mathers et al. 2009). More than one-third of adults aged 60 and over in the United States has hypertension—a condition resulting in more health care visits than any other chronic condition (Schroeder et al. 2004). Nationwide, it is estimated that only 35% of older adults with hypertension maintain target blood pressure (BP) readings (<140/90; <130/80 for those with diabetes or chronic kidney disease) (Schroeder et al. 2004; Wong et al. 2007). Inadequately controlled hypertension, owing to poor patient adherence to antihypertensive regimens and adverse-self medication behaviors, contribute to annual estimated health care costs of $100 billion (Institute of Medicine 2006; NHLBI 2007).

Older adults with hypertension were found to have low self-efficacy in their ability to avoid serious health consequences, owing to their large knowledge deficits regarding interactions between prescription and OTC agents (Neafsey and Shellman 2002a). Rather than identify and remediate low self-efficacy in patients, which results in poor adherence and adverse self-medication behaviors, uncontrolled BP is often treated with intensified antihypertensive therapy. This therapy is regularly administered with increased doses, additional agents, and/or drug changes, thus further heightening the risk of adverse drug effects (ADEs) and patient care costs (Ho et al. 2008; Peterson 2008). Moreover, clinical trials have yet to demonstrate any long-term improvement in patient adherence to antihypertensive therapy (Haynes et al. 2008). By contrast, intensive, monthly counseling by nurses or pharmacists has been shown to improve antihypertensive adherence in older adults, but BP control typically declined when the intervention ceased (Bosworth et al. 2005; Lee et al. 2006; Roumie et al. 2006).

There are a number of other causes and/or effects related to unsuccessful control of patient blood pressure level. For instance, patient reticence about reporting symptoms from medication side effects during provider visits is significantly correlated to ameliorable and preventable adverse drug events (ADEs) (Weingart et al. 2005). The number of symptoms reported during the past month is associated with the number of self-reported ADEs (Oladimeji et al. 2008). Over-the-counter (OTC) medications, supplements, and alcohol all interact with antihypertensives and contribute to poor BP control (Gurwitz et al. 2003; Institute of Medicine 2006;

Wallsten et al. 1995). For example, patients with hypertension may choose a non-steroidal anti-inflammatory drug (NSAID) to self-medicate pain (Neafsey and Shellman 2001; Neafsey et al. 2007)—without knowing that NSAIDS (e.g. ibuprofen) can increase blood pressure and antagonize the anti-platelet effects of low-dose aspirin and the effects of anti-hypertensive agents when taken concurrently (Aw et al. 2005; MacDonald and Wei 2003; Polonia 1997). Hence, it seems logical to find that educating patients about safe medication use can help reduce the risk of potential adverse drug interactions (PADI) (Gurwitz et al. 2003).

With advances in *e*-health, a tailored system could provide a cost-effective patient education tool to help increase patient knowledge and self-efficacy, and thus safe self-medication practice. The Personal Education Program (PEP) is one such network-based *e*-health intervention system that has demonstrated its effectiveness in improving safe self-medication knowledge, efficacy, and behaviors among older adults with hypertension (Neafsey et al. 2002, 2001; Strickler and Neafsey 2002). Its successor, the "next generation" PEP (PEP-NG), contains significant software and educational content enhancements. For instance, the once paper-and-pencil measurement instruments (assessing such outcome measures as medication use, medication knowledge, self efficacy, and user satisfaction) became part of the software system to enable dynamic real-time assessment of patient interface outcomes. A rules engine was added to the software system to assess self-reported self-medication behaviors and deliver tailored education to the patient.

This manuscript presents the results of an efficacy trial of the PEP-NG conducted in 11 primary care settings. The tailored, touch-screen tablet-based educational intervention is one of the first designed to reduce adverse self-medication behaviors in older patients with hypertension. In conceptualizing the study, which aimed at stimulating cognitive learning and enhancing self efficacy in patients to motivate them to adopt safe self-medication practices and modify adverse self-medication behaviors, Bandura's social cognitive theory was utilized as the general theoretical framework to guide the study design (Bandura 1997, 2001). The constructs of Bandura's Social Cognitive Theory (following, in quotes, Bandura 2001), as applied to the PEP-NG content design, encompass the following conceptual aspects: 1) "symbolizing capability" (animations in the PEP-NG form mental pictures) that give "meaning, form, contiguity" to patients' self-medication experiences to "guide future behaviors;" 2) "vicarious capability" (animations and related multiple choice questions) that enables "observational learning" so that patients can envision patterns of behavior quickly, avoiding mistakes; 3) "forethought capability" (interactive questions in the tailored-education segments) that allow patients to consider "predictive function and expectations of behavioral outcomes;" 4) "self-regulatory capability" (self-efficacy instrument and feedback from interactive questions) that motivates patients to acknowledge their confidence in performing future tasks related to self-medication; and 5) "reciprocal determinism" that enables the "bi-directional interaction" with the APRN during the focused visit following PEP-NG use.

The goal of the clinical efficacy trial (conducted in primary care settings) was to reduce adverse outcomes associated with unsafe self-medication practices in older adults with hypertension – through improved patient-provider communication—with the aid of the PEP-NG system. Trial objectives for older-adult patients were to show that users of the PEP-NG would: 1) increase knowledge concerning potential drug interactions stemming from unsafe self-medication practices; 2) enhance their self-

efficacy in learning and adopting safe self-medication practices; 3) reduce self-reported unsafe self-medication behaviors associated with potential adverse drug interactions; 4) improve their prescription medication adherence; 5) achieve and maintain target blood pressure readings; 6) express their satisfaction with the PEP-NG; and 7) enhance the patient-APRN provider relationship.

Methods

A full description of the PEP-NG instruments, interface, prior usability, pilot testing with older adults, and clinical-trial methodology can be found elsewhere (Lin et al. 2009, 2010; Neafsey et al. 2009, 2008; Strickler et al. 2008). A brief explanation of how the patient and provider utilize the PEP-NG software to achieve the study objectives is provided below, followed by a description of the research procedures adopted for the current project.

PEP-NG Interface

The PEP-NG was accessed via a wireless tablet computer*; patients used a stylus to answer questions on the touchscreen interface. In terms of on-screen display, visual objects were large (3 cm high) and text size was in a 20-point size Arial Black font to facilitate ease of reading for older adults. Ergonomically adaptive, wide-scroll bars and dropdown-menus displayed in blocks of eight lines eased selection of agents for those with impaired hand mobility and/or fine tremor. The time of medication and dosage was reported with the use of an easy-to-use animated clock. Patients were asked what they took for treating common ailments or conditions (e. g. blood pressure, blood thinning, pain, cold or sinus, allergies, sleep, stomach problems such as indigestion or gas, and low thyroid). Patients were also asked, "Did you take ____ in the last month?" with respect to calcium pills, vitamins, minerals, herbs or supplements, and alcohol, wine, or liquor.

A rules engine analyzed patient-inputted information and immediately delivered individually tailored educational content on the tablet screen. Summaries of a patient's self-reported symptoms, medication use (including frequency/time), adverse self-medication behaviors (along with a thumbnail screen shot from a related animation), and corrective strategies were automatically printed for review by the APRN provider prior to the primary care visit. The APRN reinforced the corrective education information (that appeared on the printout) with the patient as part of their primary care BP visit. At the conclusion of the APRN visit, the patient took a copy of the same printout home for self-study. A Virtual-Private-Network (VPN) transferred all PEP-NG interface data to a Microsoft Access database. The VPN met HIPAA requirements (Federal Register 2000) and the European Union Directive 95/46/EC (de Meyer et al. 1998). The interface was developed in accordance with ISO 9100 international standards (ISO 2004; Kelly 2000).

Participant Recruitment

The study was approved by the University Institutional Review Board (IRB) and met all HIPAA regulations prior to enrolling any provider or patient participants. All methods

adopted were performed in accordance with the 1964 Declaration of Helsinki and all study participants gave consent prior to participation in the study (World Medical Association 1964). Two practice-based research networks (PBRN) in New England cooperated in study site recruitment. APRNet is a PBRN of APRNs, funded by the Agency for Healthcare Research and Quality (AHRQ) and administered by the Yale School of Nursing. The Connecticut Center for Primary Care (CCPC) PBRN is an independent, non-profit corporation established (under CT law) by ProHealth Physicians, Inc.

Primary-care practice owners and APRNs affiliated with each PBRN were sent an illustrated brochure describing the study and inviting them to participate. A member of the research team gave an on-site demonstration of the PEP-NG software and study materials to APRNs interested in participating in the study. Once recruited, practices were offered free installation of a wireless-access node (meeting HIPAA requirements) and a free tablet computer (in addition to the unit used for the study) as incentives for participation. APRNs were offered $80 to compensate for their completion of the 2-h, on-site PEP-NG study training. They were also offered 10 continuing education units (CEUs) for reading 10 journal articles (related to potential adverse effects caused by unsafe patient self-medication behaviors) and subsequently completing the pre- and post-training instruments. APRNs (or the primary care practices) were also offered $55 for each participant enrolled (up to 24 participants). This payment was to compensate for the approximately 40 min of time needed to ascertain study eligibility, conduct the informed consent process, show the online tutorial to the patient, keep the participant gift-card receipts, and file recruitment reports for each patient participant.

Practices associated with the PBRN networks entered the study in an ongoing basis. A member of the research team who was in a post-masters' adult nurse practitioner program conducted the 2-h on-site training session with each APRN. Each APRN was given a research notebook with a step-by-step study protocol, instruments for assessing study eligibility, record sheets for documenting each visit, grocery gift cards, and study appointment cards. Illustrated participant recruitment brochures and posters with the APRNs' names and practice contact information were placed in waiting and examination rooms. Older adults self-referred for the study by calling the practice and making an appointment with the APRN. The APRN met with each prospective participant to review the consent form (written in an Arial 14 font at a grade-6 reading level). Participants were requested not to participate in another research study related to their health while enrolled in the PEP-NG study.

After attaining patient consent to participate, the APRNs used the following inclusion criteria to assess study eligibility: 1) not previously involved in a PEP study; 2) at least age 60 (by self-report); 3) a health literacy score of at least 44 (6th grade) as measured by the Rapid Estimate of Adult Literacy in Medicine (REALM) tool (Davis et al. 1993, 1998); 4) currently taking prescribed antihypertensive medication; and 5) independent-living and cognitive-functioning ability. The latter was reflected by the older adult's ability to: a) independently manage the tasks of telephone communication, shopping, travel arrangements, self-medicating, and finance activities, as assessed with the Instrumental Activities of Daily Living Scale, (Lawton and Brody 1969); b) successfully answer 6 of 10 items on the Short Portable Mental Status Questionnaire, (Pfeiffer 1974); and c) live independently. Eligible patient participants also needed to demonstrate a visual acuity of at least 20/100 (with corrective lenses, if needed).

APRNs selected a four-digit random number from a list (provided by the study) as the log-in ID for each participant. The APRN also selected a random number for the APRN log-in ID and another for the site ID. In order to minimize confounding effects due to the heterogeneity among APRNs and site-patient populations, the PEP-NG randomly assigned participants within each site to either the control or intervention groups. APRNs mailed the PI monthly monitoring reports with the numbers of patients, using the following metrics: a) screened for participation; b) met and not met study criteria; c) enrolled; d) dropped out of the study; and e) experienced adverse or unexpected effects such as anxiety or eye strain. APRNs were also asked to immediately report any adverse events to the PI.

APRN Training

Before the on-site training, APRNs logged on to a dedicated website to complete pre-training Rx-OTC knowledge, Rx-OTC self-efficacy, and Eldercare self-efficacy instruments. During the training session, APRNs tested the separate patient and provider interfaces of the PEP-NG. They were also given a packet of 10 articles, written by the PI, documenting the evidence that underlies the specific adverse medication behaviors addressed by the PEP-NG. After reading these articles (over the next 2 weeks), the APRNs logged on to an APRN-dedicated website to complete post-training knowledge and self-efficacy measurement instruments. The APRNs completed the post-training instruments at two different times—after successfully enrolling their sixth participant (typically 3 months later) and their twelfth participant (typically 6 months later), respectively.

Trial Protocol

Participants met individually with their APRN four times over 3 months in a private examination room at the practice site. Participants were encouraged to bring all of their medications (including supplements) to each visit. The APRN took the patient's BP at the beginning of visit 1. By attaching a keyboard to the tablet, the APRN entered the participant's year of birth (confirmed from the medical record), gender, BP, and REALM health literacy score (Davis et al. 1993, 1998) via the tailored APRN-provider interface. The APRN also entered each patient's prescribed and provider-recommended (e.g. low-dose aspirin) medications, including, dose, timing, and any special instructions for taking the medication.

Upon completion of patient data entry, the APRN removed the tablet from the keyboard and set it on a height/angle adjustable stand to ready the tablet for patient-participant use. The APRN read a tutorial script to the participant, while the participant practiced using a stylus to touch the interface and sample screens (including a question, a medication screen, a "clock" screen, and an interactive animation screen). When the participant expressed comfort with the patient interface, the APRN left the patient to begin the PEP-NG interface task independently.

On visit 1, participants completed demographic questions concerning living environment (with whom they live, type of residence), education, race/ethnicity, income (e.g. whether their monthly income is at, above, or below $1,500 per month), as well as health questions about current medical problems and symptoms. The

patient then completed all measurement items (except the satisfaction survey) and responded to questions about the medications and OTC agents they take for treating their blood pressure and common health problems. On visits 2–4, before asking the patient to continue with the PEP-NG unassisted, the APRN reviewed patient comfort with the stylus use and PEP-NG interface as needed. Demographic questions were omitted on visits 2–4. On visit 4, participants completed the patient-satisfaction instrument, in addition to the other scales and questions measured during visits 1–3. After each PEP-NG use, the participant visited with the APRN for approximately 15 min. During the visit, the APRN took the participant's BP, based on the JNC-7 standards (Chobanian et al. 2003). The APRN then recorded the BP reading and reviewed/updated any changes in the medication regimen on the provider interface.

Participants in the intervention group received tailored education in the following manner. The PEP-NG rules engine analyzed patient-entered information and delivered educational content tailored to the three patient-reported behaviors associated with the highest risk scores. The education components included: 1) animations and "medicine facts" that illustrated and described the adverse behaviors identified; 2) "what you can do" tips which offered corrective strategies; and 3) interactive questions that allowed the user to rehearse and apply the information learned. A printout generated by the patient-reported data on the PEP-NG listed patient-reported symptoms, the three identified adverse self-medication behaviors and corrective strategies suggested by the PEP-NG, along with thumbnail screen shots from the animations. In the case of fewer than three reported adverse behaviors, the PEP delivered a set of up to three default statements dealing with medication adherence, OTC pain relievers (that can be safely taken with antihypertensives), and dangers of combining different types of pain relievers (prescription and OTC). A copy of the printout was also given to the APRN to help inform the patient visit as described above.

Like their counterparts in the intervention group, participants in the control group were asked to complete all questions via the PEP-NG. They also received a general education message, an interactive animation, and an interactive question at the end of each session, which highlights how BP medicines work and emphasizes how BP medications must be taken every day. These participants did not receive a printout at the end of each of their PEP-NG uses or APRN visits.

Participants in both the intervention and control groups were offered a $10 grocery gift card at the end of each of the first three visits and a $25 grocery gift card at the end of the fourth visit to compensate for time in the study. At the end of the fourth visit, the patient was given a card with a dedicated telephone number to call—if he or she wished to schedule a 20-min qualitative follow-up interview to be conducted at the practice with a nurse researcher. The patient was given an additional $10 grocery gift card for participating in the post-trial interview. The APRNs were also invited to participate in the post-study interview and given a $25 grocery gift card as reimbursement for their time.

Outcome Measures

The Adverse Self-medication Behavior Risk, OTC-Rx Knowledge, OTC-Rx Self-Efficacy, Eldercare Self-Efficacy, and Healthcare Relationships and Satisfaction

Scales were previously validated, along with a description of their individual psychometric properties (Anderson and Spencer 2002; Neafsey 1997; Neafsey and Shellman 2002a, b; Neafsey et al. 2002, 2001, 2009; Shellman 2006). All instruments were written at a 6th-grade Flesch-Kincaid reading level (Flesch 1968). The primary-patient outcome measure was patient Adverse Self-Medication Behavior Risk Score. BP control, OTC-Rx Knowledge, OTC-Rx self-efficacy, and health care relationships and satisfaction with the PEP-NG were secondary outcome measures for patient participants.

BP measurements were taken by the APRN at each visit—at the beginning of PEP use on visit 1, and post-PEP use on subsequent visits. Inadequate BP control was defined as: 1) a SBP $\geq$ 140 mm Hg or a DBP $\geq$ 90 mm Hg for patients without diabetes; and 2) a SBP $\geq$ 130 mm Hg or a DBP $\geq$ 80 mm Hg for patients with diabetes or chronic kidney disease, per the JNC-7 guidelines (Chobanian et al. 2003).

Adverse self-medication behaviors were identified from questions that address use of medications (in the past month) to treat high blood pressure as well as use of OTC agents and alcohol for problems that were self-treated with non-prescription agents (e.g. pain, fever, colds or sinus, allergies, sleep, indigestion, gas, constipation). Participants were also asked if they drank alcoholic beverages, smoked or used nicotine, or took any vitamin or mineral supplements (including what, when and how frequently each was taken). The Adverse Self-Medication Behavior Risk Score is the weighted sum of the scores for the adverse behaviors identified (Neafsey et al. 2009).

The OTC-Rx Knowledge scale has 14 multiple-choice items and the score is the percent of the items with correct response; these items test both knowledge and application concerning potential adverse effects of self-medication with OTC agents, supplements, or alcohol in persons with hypertension. The OTC-Rx Self-efficacy scale is a 12-item instrument with statements reflecting patient confidence in selecting appropriate OTC agents and supplements, aside from avoiding adverse effects arising from self-medication behaviors. This scale has 5-point self-report response categories (ranging from 1, "Not Sure" to 5, "Totally Sure"). Responses were summed and divided by the number of items answered, so that the overall score would not be affected by omitted items and was reported based on the original 5-point metric.

The Eldercare Self-Efficacy instrument is a 7-item, 5-point Likert-type scale that assesses APRN self-efficacy in communicating with older adults about their medications (Shellman 2006; Neafsey et al. 2009). The Health Care Relationships Instrument is a 5-item instrument for patients, gauged with a 5-point Likert-type scale (ranging from "not at all easy" to "very easy") that measures patient-provider communication (two questions), trust in provider, participation in decision-making related to care, and satisfaction with care (Anderson and Spencer 2002).

The PEP-NG user Satisfaction scale is a 14-item instrument—with eight items addressing the ease of program use, program content, and suitability of program content—and another six items addressing the intent to change behavior following program use. Ratings reflected by the 5-point Likert-type scale (ranging from 1, "strongly disagree" to 5, "strongly agree") were summed and divided by the number of items answered to ensure that the overall Satisfaction scale was not affected by omitted items and was cast in the original 5-point metric.

Data Analysis

A complete description of the methods of data analysis and statistical power considerations are published elsewhere (Neafsey et al. 2009). The study design involved three factors: PEP-NG intervention vs. control, time (evaluation at baseline and at three subsequent time points), and APRN (10 advanced practice nurses). Variation in outcome measures between APRN, while likely to occur, was of secondary interest, therefore the APRN factor was treated merely as a source of random effects in statistical modeling and hypothesis testing. The principal study hypothesis concerned the possibility of differential change in the PEP-NG and control conditions between baseline and final study assessments. Although changes could be contrasted between the PEP-NG and control groups for many outcome measures, the comparison of changes in adverse self-medication risk score was of primary interest. Statistical power analysis showed that a total sample of 164 subjects (82 per group) would be sufficient to yield 80% power to detect a 5-point difference between the intervention and control groups in mean changes from baseline to visit 4 in the adverse self-medication risk score.

Repeated measures linear-mixed model ANOVA methodology was the basis of most statistical tests and effect estimations. There are three reasons why this more complex analysis tool was used instead of the simpler traditional least-squares ANOVA technique. First, each participant was measured repeatedly over time (at each of four visits); these four repeated measures are likely to be dependent, and therefore an appropriate covariance-structure must be selected to capture this feature of the data. Unlike traditional ANOVA, with mixed-model ANOVA it is no longer necessary to assume the covariance structure adheres to compound symmetry or sphericity; instead, one can choose from a large collection of covariance-structures as appropriate to the observed data. Second, patients who visit the same APRN might tend to have similar demographics characteristics, while patients across APRNs might tend to have different characteristics. Such clustering effects need to be adjusted through the estimation of random effects associated with the APRNs. Third, traditional linear model techniques drop an entire participant from the analysis if the subject has missing data at one visit, while linear mixed models allow subjects to have missing visit values. Hence, linear mixed models provide researchers with a powerful and flexible analytic tool for these kinds of data. The SAS software package (v. 9.2; SAS Institute, Inc., Cary, NC) allows a full implementation of this analytical tool through its Proc Mixed procedure (Brown and Prescott 2006; Verbeke and Molenberghs 2000; West et al. 2006).

The linear mixed models used study group (intervention vs. control) and visit (1–4) as categorical variables and controlled for gender, age, APRN, income, education, and computer use. Adjustment for computer use was performed because this variable was significantly different between study groups at visit 1. Initially, the models considered the possibility of an interaction effect between study group and visit on outcome measures. However, whenever this interaction was not found to be significant, it was dropped from the model. The potential impact of co-linearity between the income and education covariates was considered before identifying the final model for each outcome measure.

Paired-*t* tests were used for post hoc analyses of knowledge, self-efficacy, and BP within groups. Non-parametric tests (Cochran-Mantel-Haenszel statistic), based on rank scores, controlling for participant code were used for the transformed behavior

risk scores within groups. As age is significantly inversely correlated with DBP (Chobanian et al. 2003), correlations between outcome measures were conducted while controlling for age. Cross-tabulations comparing the frequencies of dichotomous assessments relative to study group were created and subjected to statistical testing through either the Pearson chi-square test or Fisher's exact test.

Results

Fifteen provider practices and 20 APRNs consented to the study. Five practices and five APRNs withdrew soon after the installation of the wireless access nodes for reasons unrelated to the study (including APRN illness, APRN job change, and practice-location change).

APRN Outcomes

Fifteen APRNs enrolled in the study and completed training. Three APRNS withdrew from the study after training and before patient enrollment; two of them for other jobs and one due to illness. An additional APRN withdrew after enrolling one participant (who did complete the four visits). The patient data from this APRN were removed from the analyses. The primary care practices had widely different patient demographics and practice characteristics. The participating practices were located in two urban centers, three small cities, two suburbs, and two rural areas. Eight of the APRNs were salaried, two were paid by the number of patients seen, and two were paid by the hour. All of the APRNs were Caucasian, with a mean age of 44.54 (9.71) (range 31–60 years). The mean APRN practice years was 8.4 (6.67) (range 1–23), and the mean nursing practice years was 18.3 (9.76), range 6–38.

Data were missing for four APRNs on the fourth observation (after the 12th participant was enrolled in each site). Therefore, APRN outcomes were analyzed from pre-training to post-training after the sixth participant was enrolled at each site (approximately 3 months post-training). APRN scores (N=11) on the Rx-OTC knowledge and Rx-OTC self-efficacy scales increased from baseline to after the APRN enrolled the sixth participant. Rx-OTC Knowledge increased from 67.7% (11%) pre-training to 80.9% (12%) post-training (two tailed t=2.94, p=.014). Rx-OTC Self-Efficacy increased from 3.82 (.61) pre-training to 4.13 (.47) 3 months post-training (two tailed t=2.49, p=.016). The mean score on the 5-point Eldercare Self-Efficacy Scale during pre-training (N=11) was 3.28 (.66), and it rose 3.67 (.67) after the sixth participant enrolled (approximately 3 months later); the increase was statistically significant (two tailed t=2.37, p=.039).

Baseline Characteristics of Patients

A total of 164 patient participants were screened for eligibility, 160 were eligible. Two patients died during the course of the study (both in the control group). Ten (6.25%) withdrew at various times during the study (five from the control group and five from the intervention group). The baseline characteristics of participating patients are shown in Table 1. There were no significant differences between the

control and intervention groups for any of the demographic variables. Baseline characteristics of the entire patient sample are described as follows. Patients had a mean age of 68.59 (8.71) and were predominantly US born (89%), Caucasian (93%) and females (78%). Twenty-three percent of them had monthly household incomes at or below $1,500. Their mean REALM scores were at the high school level (grade 10–12) and 92% had at least a high school diploma or GED. BP Measurements administered during the pre-intervention period on visit 1 revealed that 31% of all participants were not at JNC-7 BP targets.

More than half of the participants (53.7%) had three or more chronic conditions. The most common co-morbidities were high cholesterol (37.5%), arthritis (35.6%) anxiety (21.8%) and diabetes (16.25%). The majority of participants (66.8%) rated their health as very good or excellent during the preceding month. Most reported (63.2%) living with someone else and 36.8% reported living by themselves. While a med box was reported as the tool used most often (52.5%) to help them remember to take their medications, 37.5% of the participants selected, "I just remember," as their response.

The most common symptoms (during the last month reported by 20% or more of participants) were pain, fatigue, difficulty sleeping, allergies, heartburn, cough, leg cramps, anxiety and a cold. Medication labels and the pharmacist were reported as the most common sources of medication information, followed by the doctor, medication insert (dispensed by the pharmacy or the medicine package), and nurse. Participants indicated that they buy OTC medicines primarily in grocery stores and discount stores with pharmacists. Fewer than 5% of these participants reported buying OTC medicines over the Internet.

A majority (73.6%) of participants took five or more Rx medications in the past month, with a mean of 6.93 (3.41). When OTC agents were included, nearly all (98.1%) of the participants reported taking five or more different medications in the past month, with a mean of 11.41 (4.31). More than 12 medication doses per day were taken by 9.5% of the participants. The most common medications reported are profiled in Table 2. Self-reported medication adherence for antihypertensives was high, with 89% or better daily adherence reported for each category of antihypertensive. None of the participants reporting less than daily adherence on *all* antihypertensives were at BP targets upon study entry.

The mean number of antihypertensive medication formulations prescribed to the study participants upon entry to the study at visit 1 was 1.52 (0.83), with a range of 1–5. One antihypertensive medication formulation was prescribed to 63.9% of the participants, 24.3% were prescribed two, 8.11% were prescribed three, 2.79% were prescribed four, and 0.84% were prescribed five antihypertensive medication formulations.

A total of 44 different antihypertensive formulations were prescribed to the study participants upon entry to the study at visit 1. The most common were: lisinopril (10%), hydrochlorothiazide (8.1%), Toprol XL® (8.1%), atenolol (6.25%), Diovan® (4.4%), and Coreg® (4.4%). The most common antihypertensive categories prescribed were calcium channel blockers (41.9%), angiotensin converting enzyme inhibitors (ACEIs) (38.8%), beta blockers (29.4%), angiotensin II receptor blockers (ARBs) (28.1%) and thiazides (20.0%). Treatment with a single antihypertensive agent (monotherapy) was prescribed to 65.3% of the patients upon entry to the study at visit 1.

Among participants not at BP targets upon study entry at visit 1, the mean number of antihypertensive medication formulations was 1.45 (0.82), with a range of 1–4. One

Table 1 Baseline characteristics of patient participants

Characteristic	Total (N=160)	Control (n=73)	Intervention (n=87)
Age, mean (SD), years	68.6 (8.7)	69.6 (7.7)	67.8 (9.5)
Female sex (%)	125 (78.1)	60 (82.1)	65 (74.7)
Race, Ethnicity (%)			
White or Caucasian	150 (93.7)	69 (94.5)	81 (93.1)
Black or African American	3 (1.8)	2 (2.7)	1 (1.1)
Asian	1 (0.6)	0 (0)	1 (1.1)
Native American	3 (1.8)	1 (1.3)	2 (2.3)
Hispanic or Latino	2 (1.2)	1 (1.3)	1 (1.1)
Hawaiian	1 (0.6)	0 (0)	1 (1.1)
Pacific Islander	0 (0)	0 (0)	0 (0)
More than one	0 (0)	0 (0)	0 (0)
Other	0 (0)	0 (0)	0 (0)
Born in US (%)	143 (89.3)	65 (89.0)	78 (89.7)
Monthly Household Income (%)			
<$1,500 per month	20 (12.5)	11 (6.7)	9 (5.6)
About $1,500 per month	17 (10.6)	10 (6.3)	7 (4.3)
>$1,500 per month	117 (73.1)	50 (31.2)	67 (41.8)
No answer	6 (3.8)	2 (1.3)	4 (2.5)
REALM Score (SD)	65.3 (3.5)	65.4 (2.7)	65.1 (4.0)
Education, mean (SD), years	13.2 (2.8)	13.1 (2.3)	13.2 (3.1)
<12 y (%)	12 (7.5)	5 (6.8)	7 (8.0)
12 y or GED (%)	55 (34.3)	25 (34.2)	30 (34.4)
Some post-high school (%)	52 (32.5)	30 (41.1)	22 (25.2)
≥16 y (%)	41 (25.6)	13 (17.8)	28 (32.2)
BP, mean (SD), mm Hg			
Systolic	128.3 (14.6)	127.4 (13.4)	129.1 (15.5)
Diastolic	74.5 (9.5)	74.27 (8.88)	74.7 (10.1)
At target on Visit 1 (%)	110 (68.7)	49 (67.1)	61 (70.1)
Not at target on Visit 1 (%)	50 (31.2)	24 (32.8)	26 (29.9)
Mean # chronic conditions (SD)	2.7 (1.7)	2.9 (1.6)	2.6 (1.7)
Co-morbidities			
3 or more chronic conditions (%)	86 (53.7)	41 (56.1)	45 (51.7)
High blood pressure	139 (86.9)	66 (90.4)	73 (83.9)
High cholesterol	60 (37.5)	29 (39.7)	31 (35.6)
Arthritis	57 (35.6)	29 (39.7)	28 (32.1)
Anxiety	35 (21.8)	19 (26.0)	16 (18.3)
Diabetes	26 (16.3)	13 (17.8)	13 (14.9)
Irregular heartbeat	25 (15.6)	10 (13.7)	15 (17.2)

Table 1 (continued)

Characteristic	Total (N=160)	Control (n=73)	Intervention (n=87)
Osteoporosis	24 (15.0)	10 (13.7)	14 (16.1)
Depression	21 (13.1)	12 (16.4)	9 (10.3)
Asthma	17 (10.6)	9 (12.3)	8 (9.2)
Hypothyroidism	16 (10.0)	6 (8.2)	10 (11.5)
COPD	11 (6.9)	5 (6.9)	6 (6.9)
Cancer	4 (2.5)	2 (2.7)	2 (2.3)
Heart Attack	3 (1.9)	1 (1.4)	2 (2.3)
Stroke	1 (0.6)	0 (0)	1 (1.2)
Clot Legs	1 (0.6)	0 (0)	1 (1.2)
Ulcer	1 (0.6)	0 (0)	1 (1.2)
Medication Use			
Rx Meds, mean (SD)	6.9 (3.4)	6.7 (3.5)	7.2 (3.4)
Range	1–20	1–17	2–20
OTC Agents, mean (SD)	4.7 (2.3)	4.8 (2.5)	4.5 (2.0)
Range	1–12	1–12	1–12
Total (Rx + OTC), mean (SD)	11.4 (4.3)	11.2 (4.7)	11.6 (4.0)
Range	3–29	3–29	5–25
5 or more Rx medications (%)	117 (73.6)	48 (65.8)	69 (80.2)
5 or more Rx + OTC medications (%)	156 (98.1)	70 (95.9)	86 (100)
12 or more doses/day (%)	15 (9.5)	6 (8.3)	9 (10.5)
Smoking Status (%)			
Current Smoker	10 (6.2)	5 (6.8)	5 (5.7)
Using nictotine replacement	2 (1.2)	0 (0)	2 (1.2)
Alcohol Use (%)	90 (56.6)	37 (50.7)	53 (61.6)
≥3 drinks/day	2 (1.26)	0 (0)	2 (2.3)
Self-rated health in last month (%)			
Poor	1 (0.6)	0 (0)	1 (1.1)
Fair	6 (3.7)	3 (4.1)	3 (3.4)
Good	42 (26.2)	22 (30.1)	20 (23.0)
Very Good	82 (51.2)	39 (53.4)	43 (49.4)
Excellent	25 (15.6)	8 (10.9)	17 (19.5)
Living Arrangements (%)			
House	116 (72.5)	53 (72.6)	63 (72.4)
Mobile Home	3 (1.9)	2 (2.7)	1 (1.15)
Apartment	18 (11.2)	8 (10.9)	10 (11.4)
Condo	20 (12.5)	9 (12.3)	11 (12.6)
Senior Housing	3 (1.9)	2 (2.7)	1 (1.2)

Table 1 (continued)

Characteristic	Total (N=160)	Control (n=73)	Intervention (n=87)
Assisted Living	0 (0)	0 (0)	0 (0)
Other	1 (0.6)	0 (0)	1 (1.2)
Who Living With (%)			
Live by self	59 (36.8)	26 (35.6)	33 (37.9)
Spouse	73 (45.6)	33 (45.2)	40 (45.9)
Child	14 (8.8)	4 (5.5)	10 (11.5)
Other Relative	11 (6.9)	5 (6.8)	6 (6.9)
Friend	4 (2.5)	3 (4.1)	1 (1.2)
Other adult	6 (3.8)	4 (5.5)	2 (2.3)
Other	1 (0.6)	0 (0)	1 (1.2)
Tools to Help Remember Meds (%)			
Med Box	84 (52.5)	42 (57.5)	42 (48.3)
Just remember	60 (37.5)	26 (35.6)	34 (39.1)
Chart	7 (4.4)	4 (2.5)	3 (1.9)
Calendar	4 (2.5)	3 (4.1)	1 (1.2)
Cup	6 (3.8)	3 (4.1)	3 (3.5)
Other	8 (5.0)	2 (2.7)	6 (6.9)
Symptoms in last month (%)			
Pain	75 (46.9)	38 (52.1)	37 (42.5)
Fatigue	55 (34.4)	29 (39.7)	26 (29.9)
Difficulty Sleeping	45 (28.1)	20 (27.4)	25 (28.7)
Allergies	41 (25.6)	16 (21.9)	25 (28.7)
Heart burn	38 (23.8)	14 (19.2)	24 (27.6)
Cough	38 (23.8)	15 (20.6)	23 (26.4)
Leg Cramps	36 (22.5)	18 (24.7)	18 (20.7)
Anxiety	33 (20.6)	15 (20.6)	18 (20.7)
Cold	33 (20.6)	16 (21.9)	17 (19.5)
Swollen Ankles	30 (18.8)	17 (23.3)	13 (14.9)
Bruising	30 (18.8)	20 (27.4)	10 (11.5)
Weight Gain	28 (17.5)	12 (16.4)	16 (18.4)
Cold Hands	27 (16.9)	13 (17.8)	14 (16.1)
Constipation	23 (14.4)	12 (16.4)	11 (12.6)
Dizzy	20 (12.5)	8 (11.0)	12 (13.8)
Diarrhea	19 (11.9)	5 (6.9)	14 (16.1)
Depression	19 (11.9)	12 (16.4)	7 (8.1)
Irregular heart beat	17 (10.6)	5 (6.9)	12 (13.8)
Vision problem	15 (9.4)	10 (13.7)	5 (5.8)
Nicotine Craving	11 (6.9)	6 (8.2)	5 (5.8)
Skin change	11 (6.9)	4 (5.5)	7 (8.1)

Table 1 (continued)

Characteristic	Total (N=160)	Control (n=73)	Intervention (n=87)
Weight Loss	7 (4.4)	4 (5.5)	3 (3.5)
Taste or Smell Changes	7 (4.4)	0 (0)	7 (8.1)
Memory problems	7 (4.4)	2 (2.7)	5 (5.8)
Sources of Medication Information (%)			
Information on Label	110 (68.8)	41 (56.2)	69 (79.3)
Pharmacist	107 (66.9)	44 (60.3)	63 (72.4)
Doctor	84 (52.5)	35 (48.0)	49 (56.3)
Insert	49 (30.6)	22 (30.1)	27 (31.0)
Nurse	32 (20.0)	14 (19.2)	18 (20.7)
Articles	28 (17.5)	13 (17.8)	15 (17.2)
Internet	23 (14.4)	8 (11.0)	15 (17.2)
Books	11 (6.9)	9 (12.3)	2 (2.3)
Print Ads	10 (6.3)	4 (5.5)	6 (6.9)
TV	6 (3.8)	1 (1.4)	5 (5.8)
Relative	7 (4.4)	2 (2.8)	5 (5.8)
1–800 number	6 (3.8)	4 (5.5)	2 (2.3)
Friend	5 (3.1)	0 (0)	5 (5.8)
Other	1 (0.6)	0 (0)	1 (1.2)
None	0 (0)	0 (0)	0 (0)
Who helps take med (%)			
I do	152 (95.0)	71 (97.3)	81 (93.1)
Spouse	4 (2.5)	0 (0)	4 (4.6)
Child	0 (0)	0 (0)	0 (0)
Relative	1 (0.6)	1 (1.4)	0 (0)
Friend	0 (0)	0 (0)	0 (0)
Nurse	0 (0)	0 (0)	0 (0)
Other	0 (0)	0 (0)	0 (0)
Where buy OTC medicines			
Varies	0 (0)	0 (0)	0 (0)
Internet	7 (4.4)	3 (4.1)	4 (4.6)
Out of Country	0 (0)	0 (0)	0 (0)
Store with a pharmacist	129 (80.6)	59 (80.8)	70 (80.5)
Store without a pharmacist	26 (16.3)	11 (15.1)	15 (17.2)
Other	11 (6.9)	4 (5.5)	7 (8.1)
Grocery store	76 (47.5)	36 (49.3)	40 (46.0)
Discount store	54 (33.8)	19 (26.0)	35 (40.2)
Health food store	20 (12.5)	8 (11.0)	12 (13.8)
Convenience store	6 (3.8)	3 (4.1)	3 (3.5)
Other	47 (29.4)	23 (31.5)	24 (27.6)

Table 1 (continued)

Characteristic	Total (N=160)	Control (n=73)	Intervention (n=87)
Media Use			
Radio, days/week (SD)	3.8 (1.5)	3.9 (1.5)	3.7 (1.4)
TV, days/week (SD)	4.1 (1.3)	4.2 (1.4)	4.0 (1.3)
Newspaper, days/week (SD)	3.9 (1.3)	3.9 (1.4)	3.8 (1.3)
Magazine, days/week (SD)	3.9 (1.3)	4.2 (1.3)	3.6 (1.3)
PC user (%)	104 (65.4)	43 (58.9)	61 (70.1)
Days PC (SD)	6.6 (2.0)	6.6 (1.9)	6.6 (2.0)
HRs/day PC (SD)	3.4 (1.8)	3.3 (1.8)	3.5 (1.7)
Internet user (%)	98 (61.6)	37 (50.7)	48 (67.6)
Days Internet	5.8 (2.3)	6.1 (2.1)	5.7 (2.4)
Hrs/day Internet	2.4 (1.1)	2.2 (1.0)	2.6 (1.2)
Email (SD)[a]	4.9 (1.2)	5.0 (1.1)	4.8 (1.3)
Travel (SD)[a]	3.0 (1.6)	3.0 (1.6)	3.0 (1.5)
Order (SD)[a]	2.7 (1.6)	2.9 (1.7)	2.7 (1.6)
Questionnaire (SD)[a]	1.9 (1.1)	2.2 (1.2)	1.8 (1.0)
Health (SD)[a]	3.8 (1.2)	4.0 (1.1)	3.7 (1.2)
Video (SD)[a]	2.5 (1.2)	2.4 (1.2)	2.5 (1.3)

[a] 0-7 scale where 0 = never, 1 = very rarely, 7 = very often

antihypertensive formulation (containing one or more antihypertensive agents) was prescribed to 71% of the patients, 18.4% were prescribed two formulations, 5.3% were prescribed three formulations and 5.3% were prescribed four antihypertensive medication formulations. Treatment with a single antihypertensive agent (monotherapy) was prescribed for 57.9% of patients not at BP targets upon entry to the study at visit 1. (Of those participants who were at goal upon entry at visit 1, 72.5% were on monotherapy).

Table 2 Medications self-reported at visit 1

Medication category	N (%) All	N (%) Control	N (%) Intervention
NSAID	84 (53.4)	38 (52.8)	47 (54.0)
Acetaminophen	48 (30.2)	20 (27.8)	28 (32.1)
Low Dose ASA	66 (41.9)	24(31.5)	43 (50.0)
Clopidogrel (Plavix)	13 (8.2)	7 (9.6)	6 (7.0)
Decongestant	37 (23.3)	16 (23.2)	21 (24.1)
Calcium Channel Blocker	67 (42.1)	31 (43.0)	36 (41.4)
ACEI	62 (39.0)	33 (45.8)	29 (33.3)
ARB	45 (28.3)	19 (26.4)	26 (29.9)
Beta Blocker	47 (29.6)	22 (30.6)	25 (28.7)
Thiazide	32 (20.1)	19 (26.4)	13 (14.5)

In terms of offline media exposure, participants from the control and intervention groups appeared to consume radio, television, newspaper and magazine content on a similar number of days per week (3.6 vs. 4.2). Even though fewer participants from the control group were PC users than the intervention group (58.9% vs. 70.11%), this discrepancy was not statistically significant (X^2 (1, 157)=2.52, p=.1118) and both groups used a personal computer on 6.6 days per week (or nearly 7 days a week) and about 3.3–3.4 h per day. There were significantly fewer Internet users in the control group compared to the intervention group (50.7% vs. 67.6%) (X^2 (1, 157)=6.89, p=.0086), but the number of days per week (5.67 vs. 6.01) and hours per day (2.24 vs. 2.56) each group of Internet users went online was not significantly different. The number of days these two Internet user groups used the email system per week (4.82 vs. 4.97) was not statistically

Table 3 Mean knowledge, self-efficacy and risk scores and BP values (all patients)

Outcome	Visit	Control	SD	Intervention	SD
Rx-OTC Knowledge	1	45.6	14.6	45.2	16.4
	2	44.8	17.0	51.0[a]	16.5
	3	46.4	16.5	57.0[a]	15.3
	4	45.1	16.2	59.4[a,b]	16.4
Rx-OTC Self-efficacy	1	2.3	0.9	2.5	0.9
	2	2.4	0.8	2.7[a]	0.9
	3	2.6	0.8	3.0[a]	0.8
	4	2.5	0.8	3.3[a,b]	0.7
Adverse Behavior Risk Score	1	16.6	15.9	17.9	15.4
	2	12.6	12.6	16.4	13.4
	3	14.1	13.3	15.9	12.9
	4	14.2	13.5	13.4[c]	11.2
SPB mm Hg	1	127.4	13.4	129.1	15.5
	2	128.8	13.3	128.6	15.2
	3	128.6	15.9	125.8	13.2
	4	128.5	13.6	126.5	13.5
DBP mm Hg	1	74.3	8.8	74.7	10.1
	2	73.8	7.1	74.6	10.5
	3	73.0	8.0	73.0	9.8
	4	74.3	8.8	72.7	8.9

[a] Post hoc two sample t tests detected significant differences (p<.05) between intervention and control groups at visits 2, 3, 4

[b] Post hoc paired t tests detected significant increases (p<.05) within intervention group between visit 1 and visits 2, 3 and 4

[c] Post hoc paired t tests detected a significant decrease (p<.05) in transformed behavior risk score between visit 1 and visit 4

differentiated, nor was their access to different types of online content (e.g., travel and health). Lastly, the Internet self-efficacy level was not significantly different between the control-group Internet users (mean (SD)=2.03 (0.76)) and the intervention-group Internet users (mean (SD)=2.15 (0.75)) upon entry to the study. Moreover, Internet self-efficacy for both groups did not change across visits 1–4.

Patient Outcomes: All Patients

Table 3 shows the results for Rx-OTC knowledge, Rx-OTC self-efficacy, and adverse self-medication behavior risk scores, as well as BP for all patients in the study. Both control and intervention patients took approximately 43 min to answer all of the questions on visit 1 (control patients: mean (SD)=42.75 (15.6) minutes; intervention patients: mean (SD)=42.83 (15.3) minutes). Time spent on the PEP-NG for the following visits (wherein the demographic and media use questions were omitted) took approximately 25 min on visit 2 (control patients: mean (SD)=25.6 (9.0) minutes; intervention patients: mean (SD)=25.5 (11.4) minutes) and 24 min on visit 3 (control patients: mean (SD)=23.9 (8.4) minutes; intervention patients: mean (SD)=24.4 (11.0) minutes). Visit 4 repeated the media-use questions and contained the satisfaction scale. Mean (SD) time spent on visit 4 was 28.2 (8.9) minutes for control patients and 34.9 (13.3) minutes for intervention patients.

Adverse Self-Medication Behavior-Risk Score

Normality of the behavior-risk score was tested with the Shapiro and Wilk's W statistic. The skewness value was 1.4 and the kurtosis value was 2.99. The W statistic was 0.877, and normality was rejected at the 0.05 level of significance. The SAS boxcox method determined that the square-root function (square-root risk) was the best transformation of the behavior-risk score, producing a skewness value of 0.25, a kurtosis value of −0.66, and a W statistic of 0.96. Consequently, the square-root risk (transformed behavior-risk score) was used in all analyses.

While there was no significant condition by visit interaction for the transformed behavior-risk score, main effects were significant for visit (F (3, 418, $p<.0180$). There was a significant linear trend (F (1, 418)=5.18, $p=.0233$), but there was no significant quadratic or cubic trend. Results of post hoc paired t-tests and nonparametric tests showed a significant reduction in the transformed behavior-risk score for the intervention group from visit 1 to visit 4 (paired t (73)=2.17, $p=.033$; *Cochran-Mantel-Haenszel statistic* (1, 161)=4.44, $p=0.035$).

Rx-OTC Knowledge

Knowledge scores were normally distributed. The interaction between visit and condition was significant (F (3, 411)=7.15, $p=.0001$). Main effects were significant for computer use (F (1, 139)=5.67, $p=.0186$), gender (F (1, 139)=24.1, $p<.0001$), condition (F (1, 139)=20.51, $p<.0001$), and visit (F (3, 411)=10.07, $p<.0001$). There was a significant linear trend for visit alone (F (1, 411)=26.76, $p<.0001$) and for visit within the intervention group (F (1, 411)=36.51, $p<.0001$). Post hoc analyses detected significant differences between the control and intervention group

at visits 2, 3 and 4, with a large effect size on visit 4 (Cohen's d=0.877). Within the intervention group, there was a significant difference between visit 1 and 2, 2 and 3, and 3 and 4. There was also a significant increase in knowledge from visit 1 to visit 4 for the intervention group (paired t (73)=6.26, p<0.0001). Post hoc paired t-tests showed no significant change in knowledge from visit 1 to visit 4 for the control group. The main effect of being a computer user resulted in a larger knowledge score overall of 5.2 in the percent correct. By contrast, the main effect of gender resulted in males having a lower knowledge score overall of |- 9.97| in the percent correct. Rx-OTC knowledge scores were significantly correlated with Transformed Behavior risk score for the control group on visit 4 (Spearman r (141)=.41, p=.0007).

Rx-OTC Self-Efficacy

Self-efficacy scores were normally distributed. The interaction between visit and condition was significant (F (3, 412)=9.33, p<.0001). Main effects were significant for condition (F (1, 139)=9.67, p=.0023) and visit (F (3, 412)=23.68, p<.0001). There was a significant linear trend for visit alone (F (1, 412)=70.52, p<.0001), in addition to visit within the both the control group (F (1, 412)=5.15, p=.0237) and the intervention group (F (1, 412)=61.70, p<.0001). Post hoc analyses detected significant differences between the control and intervention group at visits 2, 3 and 4, with a large effect size on visit 4 (Cohen's d=1.06). There were significant differences between visits 1 and 2, 2 and 3, as well as 3 and 4 in the intervention group. Post hoc paired t-tests showed a significant increase in self-efficacy from visit 1 to visit 4 for the intervention group (t (73)=10.38, p<0.0001). There was no significant change in self-efficacy from visit 1 to visit 4 for the control group.

With the exception of Rx-OTC knowledge scores and Transformed Behavior Risk scores on visit 4 in the control group as described above, correlations were weak among Transformed Behavior Risk, Rx-OTC knowledge scores, Rx-OTC self-efficacy scores, and education. These variables were not correlated with SBP or DBP at any visit for either controls or intervention patients.

Blood Pressure

Both SBP and DBP values were normally distributed. There was no significant interaction between visit and condition for either SBP or DBP. Main effects on SBP were significant for age (F (1, 139)=4.22, p=.0419), income (F (1, 139)=6.41, p=.0125), and condition (F (1, 139)=5.50, p=.0204). There was no linear, quadratic or cubic trend. The main effect of age resulted in a larger SBP overall of 0.25 mm Hg per year (i.e. an increase of 10 years in age added 2.5 mm Hg overall to SBP). The main effect of higher income (above $1,500 per month) was a lower SBP overall of -2.68 mm Hg. The main effect of being in the control condition was a higher SBP overall of 3.6 mm Hg. Post hoc paired t-tests did not reveal any significant differences in the SBP of visit 1 with visits 2, 3 or 4 within either group.

Main effects on DBP were significant for computer use (F (1, 139)=4.73, p=0.0314) and condition (F (1, 139)=5.69, p=.0184). There was no linear, quadratic or cubic trend. The main effect of being a computer user resulted in a higher DBP overall of 2.37 mmHg. Moreover, the main effect of being in the control condition was a larger

Table 4 Degree of satisfaction and intent to change

	Control (n=64)	Intervention (n=71)
	Mean (SD)[a]	Mean (SD)[a]
Satisfaction Statement		
The movies were useful.	4.0 (0.6)	4.1 (0.7)
The questions were useful.	4.1 (0.6)	4.2 (0.5)
The program was easy to use.	4.4 (0.6)	4.4 (0.6)
The program was fun to use	4.1 (0.7)	4.2 (0.7)
The program was easier to understand than medicine labels.	3.9 (0.8)	4.2 (0.7)
Much of the information in the program was new for me.	3.6 (0.8)	4.1(0.7)*
I will recommend this program to my friends.	4.1 (0.7)	4.2 (0.6)
I would choose to other programs like this one in the future.	4.2 (0.6)	4.1 (0.7)
The advice in the program suited my special needs.	3.8 (0.8)	4.2 (0.6)*
Overall mean satisfaction score	**4.0 (0.4)**	**4.2 (0.5)***
Intent to Change Statement:		
This program helped me want to change *how* I use medicines.	3.6 (0.9)	4.2 (0.7)*
After using this program *I will make some changes* in how I use medicines.	3.4 (1.0)	4.0 (0.9)*
After using this program I will change *when* I take some medicines.	3.4 (1.0)	4.0 (0.9)*
This program helped me think of questions to ask my doctor.	4.0 (0.7)	3.9 (0.8)
This program helped me think of questions to ask my pharmacist.	3.8 (0.7)	3.8 (0.8)
This program helped me think of questions to ask my APRN	4.1 (0.7)	3.9 (0.8)
Overall mean intent to change score	**3.7 (0.7)**	**4.0 (0.6)***

[a] Mean degree of agreement with statement; 1 = strongly disagree to 5 = strongly agree

*Two sample t test significant difference (p<.05) between groups

DBP overall of 2.18 mmHg. Post hoc paired t-tests did not reveal any significant differences in the DBP of visit 1 with visits 2, 3 or 4 within either group.

The percentage of control group participants not at their BP target went from 32.9% on visit 1 to 31.3% by visit 3. This represents a 4.8% reduction in the percentage of control group participants not at BP targets at visit 3 compared to visit 1. The percentage of control group participants not at BP targets was at 35.3% by visit 4 (an increase of 7% compared to visit 1). The percentage of intervention participants not at their BP target went from 29.9% on visit 1 to 21.8% by visit 3. This represents a 27% reduction in the percentage of intervention participants not at goal at visit 3 compared to visit 1. The percentage of intervention participants not at goal was at 26% on visit 4 (a reduction of 13% compared to visit 1).

Satisfaction With PEP-NG

Satisfaction scores are shown in Table 4. Participants in both groups indicated a high level of satisfaction with aspects of the PEP-NG interface and program. Compared to

the control group, the intervention group had significantly higher overall mean satisfaction scores (t (132)=2.04, p=.0431). Post hoc t-tests revealed significantly higher ratings in the intervention group on two satisfaction items: "Much of the information in the program was new for me," (t (132)=3.83, p=.0002) and "The advice in the program suited my special needs," (t (132)=3.14, p=.0016).

The intervention group had a significantly higher "mean intent-to- change" score compared to the control group (t (132)=2.16, p=.033). Post hoc t-tests revealed a significantly greater score for the intervention group on three intent-to-change items: "This program helped me to want to change *how* I use medicines," (t (132)=4.04, p=.0001), "After using this program *I will make some changes* in how I use medicines," (t (132)=3.424, p=.0008), and "After using this program I will change *when* I take some medicines," (t (132)=3.60, p=.0005).

Satisfaction With the APRN Provider Relationship

Scores (SD) on the 5-point Likert type Healthcare Relationships Scale were similar for the control group (4.46 (0.83), n=69) and the intervention group (4.40 (0.68) n=82) participants upon entry to the study on visit 1. On visit 4, scores (SD) remained high with means of 4.42 (0.63) for the control group (n=65) and 4.34 (0.60) for the intervention group (n=75).

Patient Outcomes: Patients not at BP Targets Upon Entry to the Study

Sub analyses conducted for the study participants in both groups not at BP targets upon entry to the study are given in Table 5.

Table 5 Mean risk scores and BP values (patients not at BP targets upon entry to study on visit 1)

Outcome Measure	Visit	N	Control	SD	N	Intervention	SD
Adverse Behavior Risk	1	24	20.8	19.5	26	23.3	19.8
	2	23	15.4	13.0	23	16.1	12.0
	3	21	15.1	11.1	22	13.9	10.4
	4	21	18.5	15.1	22	11.7*	8.2
SBP mm Hg	1	24	139.9	10.7	26	146.2	9.8
	2	23	133.7*	15.8	25	139.0*	16.4
	3	21	130.5	21.4	23	129.0*	13.9
	4	21	133.8*	13.3	22	130.6*	11.5
DBP mm Hg	1	24	77.5	8.3	26	81.1	11.6
	2	23	73.6	7.0	25	79.5	13.1
	3	21	71.1*	6.7	23	76.7	11.4
	4	21	75.2	8.8	22	74.8*	9.2

* Post hoc paired t tests detected significant decrease (p<.05) compared to visit 1

Adverse Self-Medication Behavior Risk Score

There was a significant visit effect for transformed behavior risk score for those participants not at BP targets upon entry to the study (F (3, 125)=2.75, p=.0454). There was no interaction with condition or gender. While there was a significant linear trend (F (1, 125)=4.31, p=.040), there was no quadratic or cubic trend. There was a 49.8% reduction in the Behavior Risk Score on visit 4 for the intervention patients who were not at BP targets upon entry to the study. Results of post hoc paired t-tests and nonparametric tests showed a significant reduction in transformed behavior risk score for the intervention group from visit 1 to visit 4 (paired t (21)=2.41, p=.0253; *Cochran-Mantel-Haenszel statistic* (1, 48)=5.76, p=.0164).

Blood Pressure

There was no significant interaction between visit and condition for SBP among participants not at BP targets on study entry. Main effects on SBP were significant for income (F (1, 34)=4.44, p=.0425) and visit (F (3, 129)=9.54, p<.0001). There was a significant linear trend for visit alone (F (1, 129)=20.26, p=<.0001), and a significant quadratic trend for visit alone F (1, 129)=7.14, p=<.0085). There was also a significant linear trend for visit within both the control (F (1, 126)=6.27, p=.0136) and intervention (F (1, 126)=21.53, p=<.0001) groups. The main effect of higher income (above $1,500 per month) was a lower SBP overall of |−5.2| mmHg (both groups considered together). Post hoc paired t-tests showed significant reductions in SBP from visit 1 to visit 4 in both the control (−6.11 mm Hg) (t (20)=2.22, p=.0380) and the intervention (−15.51 mm Hg) (t (21)=5.95, p<.0001) groups. The intervention group had a medium effect size in reducing SBP (Cohen's d=.2548) among patients not at BP targets upon entry to the study. Post hoc paired t-tests also showed significant declines for SBP in the intervention group from visit 1 to visit 2 and 3.

Main effects on DBP were significant for visit (F (3, 129)=3.48, p=.0178). There was a significant linear trend for visit alone (F (1, 129)=8.04, p=.0053). There was also a significant linear trend for visit within both the control (F (1, 126)=4.68, p=.0324) and intervention (F (1, 126)=3.92, p=.0498) groups. The decline in DBP (−2.31 mm Hg) in the control group from visit 1 to visit 4 was not statistically significant. By contrast, the intervention group had a 2.70 fold greater decline in DBP (−6.26 mm Hg) from visit 1 to visit 4 compared to the control group, which was statistically significant (paired t (21)=3.70, p=.0013).

Among all patients (both groups) *at* BP targets upon entry to the study who reported being Internet users, Internet Self-efficacy was significantly correlated with Rx-OTC self-efficacy on visit 4 (Spearman r (50)=.4417, p=.0015). Among the control group participants *not* at BP targets upon entry to the study, Transformed Behavior Risk score was significantly correlated with SBP on visit 2 (Spearman r (21)=.51298, p=.0207) and Rx-OTC Knowledge scores on visit 4 (Spearman r (22)=.64312, p=.0017).

In patients who were not at BP targets at study entry, movement to controlled BP was uneven, but not significantly different, between the intervention and control

groups. Among 22 patients not at BP targets in the intervention group at visit 1, 14 (63.6%) had controlled BP at visit 4. In contrast, among 21 patients initially not at BP targets in the control group, only 8 (38.1%) had controlled BP at visit 4. The odds ratio comparing frequencies of these changes between groups was 2.84 (X^2 (1)=2.81, p=0.094, 95% CI: [0.83, 9.80]).

Changes in Patient Behaviors Affecting BP

Adherence was considered to be the percentage of patients reporting taking *all* of their antihypertensive medications "daily." Of patients not at BP targets on visit 1 (both control and intervention groups), 93% self-reported taking all of their antihypertensives daily upon entry to the study. Self-reported daily adherence rose to 100% of patients in both groups of patients on visit 2 and remained at 100% of patients on the ensuing 2 visits for the intervention group, while 95% of control patients reported daily adherence on visits 3 and 4. Among control patients *who were at BP targets* upon entry to the study, self-reported adherence declined over time to 87% by visit 4. Self-reported daily adherence stayed close to 95% or greater during the subsequent three visits for intervention patients who were at BP targets on study entry.

More than half of patients not at BP targets upon entry to the study reported NSAID usage in the previous month (54.2% of control and 57.7% of intervention patients). Patients in the intervention group reduced self-reported NSAID use over time from 57.7% upon study entry to 9.09% on visit 4, while 42.8% of the control group still reported NSAID usage at visit 4. Monthly NSAID use was categorized as: 1) 1–10 days/month; 2) 11–20 days/month; 3) 21–31 days/month; and 4) other. Results of a Cochran-Armitage test for trend detected a significant declining linear trend in proportion of the intervention patients in category 3 (taking NSAIDs 21–31 days/month) (Z (35)=2.5023; Exact test one sided p=.0084).

Alcohol has a pressor effect in a dose-related manner beginning at >2 drinks/day (World Hypertension League 1991). Among patients not at BP targets upon entry to the study, 41.4% of controls and 57.7% of intervention patients reported daily alcohol consumption. None of the control-group patients and two of the intervention-group patients reported having three or more drinks daily in the month prior to study entry. Both of these intervention-group patients reduced their self-reported daily alcohol consumption to one drink/day. (One reduced to one drink per day by visit 2, the other reduced to one drink by visit 3. Both of them reported one drink per day on visit 4).

Decongestants can increase BP to a variable degree—depending on agent, dose, and duration of use (Johnson and Hricik 1993; Kollar et al. 2007; Salerno et al. 2005)—but effects in older adults have not been well studied. Five (20.8%) of the control group patients and 6 (23.1%) of the intervention group patients not at BP targets upon study entry reported taking a medication containing a decongestant on visit 1. Of these patients, (40%) in the control group and three (50%) in the intervention group reported taking the decongestant medication daily. On visit 4, 6 (28.6%) in the control group and 3 (13.6%) in the intervention group reported taking a medication containing a decongestant in the previous month. The ability of the PEP-NG to capture decongestant taking behaviors was limited for the following

Table 6 Changes in antihypertensive regimen made by provider (Of patients not at BP targets upon entry to study on visit 1)

	Control (n=24) Change (%)	Intervention (n=26) Change (%)
No Change	15 (62.5)	16 (61.5)
Increased Dose	4 (16.7%)	0 (0)
Added Rx	7 (29.2)	1 (3.9)
Switched Rx	3 (12.5)	3 (11.5)
Decreased dose	2 (8.3)[a]	3 (11.5)[b]
Discontinued Rx	0 (0)	2 (7.7)

[a] 2 patients, each with 1 prescription

[b] 3 patients, 5 prescriptions total

Note: In cases where an Rx was "switched" – the Rx were not also considered as "added Rx" or "discontinued Rx"

reasons: 1) decongestant taking behaviors may be episodic in nature due to seasonal allergies and colds; 2) OTC cold medications underwent reformulation during the trial period to replace pseudoephedrine with phenylephrine; and 3) study entry was on a rolling basis. Therefore, data on decongestant taking behaviors were not analyzed for time trends.

Provider Changes to Antihypertensive Regimen

Table 6 shows changes made in patient antihypertensive regimens during the study period for patients not at BP targets on visit 1. For controls, 11 (45.8%) patients not at BP targets on visit 1 had either an increase in dose or an added antihypertensive Rx. Only one intervention patient (3.85%) had an added antihypertensive Rx and none had a dose increase. For controls, 2 (8.33%) of patients had either a decrease in dose or an antihypertensive Rx discontinued. For intervention patients, 5 (19.32%) had either a decrease in dose or an antihypertensive Rx discontinued. A Fisher's exact test on therapy intensification (the number of patients receiving an increased antihypertensive dose and/or an additional antihypertensive) was significant (p=.001) with an odds ratio of 21.27, 95% CI: [2.45, 200] for the control group compared to the intervention group.

NSAID Use Among Patients Taking Daily Low-Dose Aspirin

Providers may recommend low-dose aspirin for patients with hypertension because of its antiplatelet effects and its contribution to lowering BP in the morning hours, if taken in the evening prior (Hermida et al. 2005). Resistance to the antiplatelet effects of low-dose aspirin may be due to low adherence rates to low-dose aspirin therapy, genetic polymorphisms, or high platelet counts (Tran et al. 2007). Another potential cause of aspirin resistance is frequent concurrent use (3 days or more per week) of NSAIDs (Gladding et al. 2008; MacDonald and Wei 2003; Tran et al. 2007). As shown in Table 2, 31.5% of control-group patients and 50% of intervention-group

patients reported taking daily low-dose aspirin at visit 1 upon entry to the study. Of patients taking daily low-dose aspirin, 44.7% of control and 45.4% of intervention group patients reported taking NSAIDs on a frequent basis of 3 days a week or more (26.3% of all control and 36.4% of all intervention patients who reported taking daily low-dose aspirin also reported taking an NSAID daily).

Among patients not at BP targets upon entry to the study, 71% of controls and 65% of intervention group patients reported taking daily low-dose aspirin at visit 1 upon entry to the study. Of these, 58.8% of control and 64.7% of intervention group patients also reported taking NSAIDs on a frequent basis of 3 days a week or more; 29.4% of these controls and 52.9% of these intervention patients reported taking an NSAID daily. By visit 4, 69.2% of the controls and *none* of the intervention participants who indicated taking daily low-dose aspirin reported frequent NSAID use of 3 days a week or more (30.8% of control patients who reported taking daily low-dose aspirin still reported taking an NSAID daily on visit 4). Categorizing monthly NSAID use as described above and applying the Cochran-Armitage test for trend detected a significant declining linear trend across the four visits, in proportions of intervention participants who took NSAIDs 21–31 days/month ($Z(29)=2.6049$, Exact test one sided $p=.0062$). There were *no* significant trends in NSAID use among patients in either group who *were* at BP targets upon entry to the study, regardless of low-dose aspirin use.

Antihypertensive/NSAID Combinations That Can Impair Renal Function

Taking NSAIDs with the combination of diuretics and either ACEIs or ARBs increases the risk of renal impairment in older adults (Juhlin et al. 2005; Loboz and Shenfield 2004). Among all participants in the study, 15.7% took either an ACEI or ARB and took a diuretic and NSAIDs concurrently in the previous month on visit 1. By visit 4, this combination was taken by 23.5% of control-group patients, compared to 12% of intervention-group patients. Among patients not at BP targets upon entry in to the study, 33.3% of the control group and *none* of the intervention-group participants were taking this nephrotoxic combination on visit 4. Among the control-group participants not at BP targets on visit 1– in five of seven cases where a Rx was added to the antihypertensive regimen—the Rx added was a diuretic; in four of these cases, the patient also reported taking an NSAID (other than low-dose aspirin) in the previous month. In two of the four cases where an antihypertensive dose was increased to control BP, the agents were diuretic/ACEI combinations and both of these participant also reported taking NSAIDs in the previous month.

Discussion and Conclusions

Discussion

Older adults' risk of potential adverse drug interactions (PADI) is greatly increased when they have three or more chronic illnesses, take five or more concurrent medications, ingest more than 12 medication doses taken per day, have a history of nonadherence, or take a drug that requires therapeutic monitoring (Isaksen et al. 1999). In the current study, 53.7% of the participants had three or more chronic illnesses, 98%

reported taking five or more different medications in the past month (combining both Rx and OTC medications), and 9.5% took 12 or more medication doses per day. This suggests that nearly all of the participants were at risk for a PADI. That 37% of patient participants selected "just remember" as the only means that helps prompt them to take their medications is disconcerting and supports past findings that older adults make infrequent use of medication management tools (Lakey et al. 2009).

Satisfaction with the PEP-NG interface and the APRN provider relationship were high in both the intervention and control groups. The intervention group had significantly higher scores on the "intent to change" subscale. Both groups in the current study had high mean scores on the "health care provider relationship" scale, indicating a high degree of trust in and satisfaction with their care, as well as feeling involved in their health care decisions and an ease and comfort in communicating with their APRN provider.

Compared to the control condition, participants in the intervention group demonstrated significant increases in both Rx-OTC self-medication knowledge and self-efficacy measures (with large effect sizes) via repeated measures. Moreover, patients in the intervention group did not need more interface time to complete the longer education/learning-outcome assessment content than those in the control group to achieve increased knowledge and self-efficacy. These results could be indicative of the user-friendly nature of the tailored PEP-NG system—which enables the users to tailor their own learning style and focus to maximize their learning outcomes—such as concentrating on remedying their riskiest self-medication behaviors (as revealed by the PEP-NG's built-in risk-score calculation metrics). These findings provide a strong testament to the advantage of an *e*-health intervention with tailored content and an interface design which was iteratively tested and validated for system usability and content usefulness (see Lin et al. 2009, 2010).

The study evidence shows that SBP and DBP declined in both intervention and control-group patients who were not at BP targets upon study entry. However, the decrease in the intervention group was more than two-fold greater than that in the control group having both clinical *and* statistical significance. A report prepared for the Agency for Healthcare Research and Quality (AHRQ) documented the mean reductions in SBP and DBP as 4.5 mm Hg and 2.1 mm Hg respectively, across all studies examined and a variety of BP management strategies (Shojania et al. 2005). The present study found mean BP reductions of 15 mm Hg for SBP and 6 mm Hg for DBP among the intervention-group participants. According to unbiased estimates of efficacy from a recent meta-analysis of BP reduction and cardiovascular outcomes (Law et al. 2009), a reduction of 10 mm Hg in systolic BP or 5 mm Hg in diastolic BP reduces coronary heart disease events by 22% and stroke by 41%.

The manner in which patients moved to BP targets in the current study differed between the intervention and control groups. Providers intensified antihypertensive therapy by adding new antihypertensives and/or increased doses with an OR of 21.27 in the control group, compared to the intervention group. The intervention group changed behaviors that counteracted the efficacy of antihypertensives—by significantly decreasing NSAID use and intake frequency—and, in two cases, decreasing alcohol consumption. Self-reported adherence (taking all antihypertensives daily) reached 100% in the intervention-group participants who were not at BP targets upon entry to the study. Of particular concern is that therapy intensification in the control patients not at BP targets upon study entry resulted in placing 33 t% of

those patients at added renal risk because of continuing, concurrent NSAID use. The American Geriatrics Society guidelines specifically note that this so called "triple whammy" (Loboz and Shenfield 2004) combination (ACEIs/ARBS, thiazides, and NSAIDS) should be strictly avoided (American Geriatrics Society 2009).

Upon entry to the study, 53.4% of participants reported taking NSAIDs in the previous month, a practice that should be avoided in older patients with hypertension, because NSAIDs both increase BP as well as counteract the efficacy of antihypertensives and low-dose aspirin (American Geriatrics Society 2009). The current study findings were somewhat dissimilar to the results reported by a recent cross-sectional home-interview study. This particular study, a nationally representative probability sample of 3,500 older adults, examined the use of Rx and OTC agents by ranking specific medication ingredients (rather than categories of agents); none of the NSAIDs were mentioned among the top 20 most commonly used medications by study participants (Qato et al. 2008). Qato et al. (2008) also found lower rates of low-dose aspirin use among their study participants (28%), compared to the participants in the current study (41.9%).

Among intervention participants not at BP targets upon entry to the study, NSAID use was greatly reduced by visits 2–4, both in terms of numbers of patients reporting any NSAID use and frequency of use. This likely had a major influence on the greater reductions in both SBP and DBP in the intervention group. The findings that NSAID usage significantly declined only among intervention patients not at BP targets upon study entry, but not among control group patients or patients in either group who were at BP targets upon study entry, is an important one, suggesting that patients whose BP was under control were less likely to heed advice to avoid self-medication with NSAIDs.

It is also of interest that none of the participants who reported less than daily adherence for all of their antihypertensives were at BP targets upon study entry. Patients who self-report nonadherence, as identified by their answer to the question—"In the last month, how often did you take your medications as your doctor prescribed?"—have as great a cardiovascular risk as patients who smoke or have diabetes (Gehi et al. 2007). While the PEP-NG may over estimate adherence and cannot provide precise adherence data, nonadherence documented on the PEP-NG printout can foster patient-provider communication about reasons the patient did not adhere to the prescribed therapy.

Limitations

The study design consisted of four monthly APRN provider visits. This intervention design may be considered a study limitation, as clinical interventions involving repeated visits have resource and workflow barriers to widespread implementation in a clinical setting. Another potential limitation associated with this study is that the BP measurements were taken by the participating APRN and could be subject to observer bias. As patients self-referred to the study, the percentage of patients not at BP targets at study entry (31.2%) may not have been representative of the patient population at the practice sites and was not representative of the U.S. as a whole (Chobanian et al. 2003). In general, participants were predominantly female, Caucasians; they also had higher health literacy (REALM) scores, education attainment, and self-health ratings than the population of adults aged 60 and older with hypertension (Bennet et al. 2009).

Therefore, participants may not reflect the general population of patients in the primary care practices with respect to either demographic characteristics or degree of adherence to their antihypertensive regimen. While the characteristics of the participants limit generalizability of study results, the findings do support the feasibility of a content-tailored *e*-health intervention with older adults in primary care practices.

Despite fairly homogeneous participant characteristics, participants did have income diversity with 23% reporting a monthly income at or below $1,500. The results suggest that income did not play a role in Rx-OTC knowledge and self-efficacy scores, adverse self-medication risk scores, or BP. Gender was found to have a main effect in Rx-OTC knowledge scores (with approximately a 10% lower knowledge score overall for males); this suggests that older men in the study were less likely to obtain information on OTC agents and their interactions with antihypertensives. Computer users had an overall 5% higher Rx-OTC knowledge scores; this indicates that prior computer-use experience may provide a small advantage in learning from computer-based education programs or seeking knowledge about medications and OTC agents from computer-based sources.

The finding that Rx-OTC knowledge was significantly correlated with transformed adverse self-medication risk scores for the control group on visit 4 suggests that knowledge alone does not necessarily transfer to safe medication-taking behaviors. This is because patient self-efficacy is a key motivating factor for behavioral adoption and change, as evidenced by the large effect size found in both knowledge and self-efficacy for the intervention group. These findings confirm Bandura's theory that knowledge and self-efficacy are separate domains and *both* are essential to effecting positive behavior change (Bandura 1997). Naturally, the role of patients' computer and Internet efficacy should also be considered when implementing an *e*-health intervention program. As suggested by past literature, while a large percentage of older adults have basic computer and Internet-use skills, they are also intrigued by and enthusiastic about becoming more computer and Internet literate (Alemagno et al. 2004; Lin et al. 2009; Nahm et al. 2004).

Conclusions

With the median time of a primary care visit at 14 min (Hing et al. 2006), providers lack the time to elicit patient medication-taking behaviors or conduct a comprehensive review of medications taken on a regular basis (Tarn et al. 2009). The provider support offered by the PEP-NG printouts (symptoms, Rx, and OTC agents taken, including frequency and timing) can free up time for the provider to engage in the sorely needed provider-patient communication by reinforcing the patient-tailored education outcomes derived from the PEP-NG interface. PEP-NG use implanted during patients' "waiting-room time" can identify their symptoms and those with PADIs, in addition to allowing them to initiate an *e*-health education experience that is tailored to their specific self-medication behaviors.

As demonstrated by the current study, an on-site *e*-health intervention combined with provider-patient follow-up communication has produced significant and positive health outcomes for study participants. As patients took only 25 min to interface with the PEP-NG on the two follow-up visits, which omitted demographic, media use, and satisfaction questions, a repeated *e*-health intervention procedure is

both feasible and doable in a clinical setting. As the current PEP-NG intervention was able to generate large effect sizes on knowledge and self-efficacy, by omitting the knowledge and self-efficacy scales in follow-up visits, the concern about time efficiency should also be mitigated.

The study described herein is an efficacy trial in the "realistic setting" of primary care practice. Additional studies of provider workflow using the PEP-NG and health care utilization costs are under way. A cost-benefit analysis (CBA) using data from time-motion studies and 52-week health care utilization data (i.e. total number of provider visits, emergency room visits, and hospitalizations) following each participant's entry to the study is being conducted and will be reported separately.

Future study with the PEP-NG will involve implementation on a wider scale with both provider-site and in-home access to the PEP-NG portal. Patients who are Internet users will be allowed to complete the program at home with reports generated to their provider prior to their office visits. This could greatly reduce the numbers of patients who would need to use the PEP-NG on-site at the provider's office and permit wider implementation in a given primary care practice. The target audience of the PEP-NG will also be expanded to patients diagnosed with pre-hypertension (BP greater than 120/80 but lower than BP targets).

The patient gains found in the current clinical trial resulting from the *e*-health intervention suggest that the PEP-NG system can be instrumental in facilitating better patient care in the primary care setting. A cost-effective and time-efficient e-health intervention system such as the PEP-NG can become a model for guiding other self-management and medication-adherence interventions directed at other major national health problems, such as diabetes, heart failure, etc., to help stem the escalating health care costs in our nation.

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* The tablet PC (Motion LE 1600 Centrino) was manufactured by the Motion Computing, Inc. in 2006. Technical specifications for this model include: Intel Pentium® M Processor LV 778 (1.6 GHz), Integrated Intel PRO Wireless 2915ABG, 512MB RAM, 30GB HDD with View Anywhere Display (to eliminate glare from overhead fluorescent lights), 12.1" wide view XGA TFT display, convertible keyboard, 3-M privacy filter, and Genuine Windows® XP.

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