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Effect of Self-Efficacy and Social Support on Adherence to Antihypertensive Drugs

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Abstract

Study Objective—To determine the relationship between poor adherence and self-efficacy or social support after a pharmacist intervention.

Design—Post-hoc analysis of data from two randomized controlled trials of physician-pharmacist collaborative interventions (6 and 9 mo, respectively) to improve blood pressure control.

Setting—Eleven university-affiliated primary care clinics.

Patients—Five hundred eighty-four patients (aged 21-85 yrs) with uncontrolled primary hypertension; 296 were in the intervention group and 288 were in the control group.

Intervention—Pharmacists provided intensified hypertension management and drug adherence counseling to patients in the intervention group.

Measurements and Main Results—Social support and self-efficacy questionnaires were administered at baseline and end-of-study visits. Patient adherence was monitored by using the Morisky self-reported adherence questionnaire. Self-reported adherence scores improved significantly in the control group (p=0.0053) but not in the intervention group; however, adherence at baseline in both groups was high. There were small, but significant, improvements in

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self-efficacy ($p<0.04$) and social support ($p<0.05$) scores in the intervention group but not the control group at the end of the study. Social support and, to a lesser extent, self-efficacy improved as a function of duration of study participation (9-mo vs 6-mo intervention), regardless of whether the patient received the intervention. Blood pressure control in both groups improved significantly at the end of the study; however, mean blood pressure was significantly lower in the intervention group (129.7/76.6 mm Hg) compared with the control group (140.8/78.9 mm Hg; $p<0.0001$ for systolic, $p=0.032$ for diastolic).

Conclusion—Social support and self-efficacy improved significantly in the intervention group at the end of the pharmacist intervention. Drug adherence was correlated with self-efficacy even though drug adherence did not improve significantly in the intervention group. The fact that social support and self-efficacy improved as a function of duration of study participation suggests that participation in a research study may have had a positive influence on these measures. Even though the changes in social support, self-efficacy, and drug adherence were modest, there was significantly better blood pressure control in the intervention group compared with the control group. These findings indicate that changes in drug adherence, self-efficacy, or social support probably played a minor role in the blood pressure outcomes in these studies.

Keywords

hypertension; adherence; social support; self-efficacy; team care; pharmacist management; research methods

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Many factors have been shown to be associated with poor blood pressure control.[1] Achieving better blood pressure control decreases the risk of serious cardiovascular events such as stroke and myocardial infarction.[2-4] Patients generally need to be adherent to their antihypertensive drug regimen in order to achieve high blood pressure control rates.[5] Poor adherence to antihypertensive therapy often results in poor blood pressure control and may lead the physician to unnecessarily increase the dose of antihypertensive drugs or add additional antihypertensives. Whereas some patients have adverse effects that interfere with drug adherence, some studies have found that adverse symptoms may decrease as blood pressure comes under control.[6] There are many barriers to drug adherence including a higher number of antihypertensive agents, bothersome adverse effects, low socioeconomic status, and personal beliefs regarding the treatment of hypertension.[7-10] Factors associated with higher rates of adherence include female gender, younger age, higher education, higher socioeconomic status, and fewer antihypertensive drugs.[5] Other studies have found those taking more drugs, especially older individuals with several chronic diseases, have better adherence.[11]

Some studies have shown that self-efficacy and social support can have a positive influence on drug adherence.[5, 7, 12-14] Self-efficacy is the ability of patients to take their drugs in various situations such as when they travel, do not feel well, or have adverse effects and their ability to integrate drug administration into their daily life.[15-19] Social support evaluates family communication and relationships and the support patients receive from their families.[14, 20] There is evidence that higher levels of self-efficacy or social support can improve drug adherence.[7, 12, 14] The purpose of our study was to evaluate the relationship

between self-efficacy, social support, and drug adherence, and to determine if a pharmacist intervention influenced drug adherence by improving self-efficacy or social support.

Methods

This study was a post hoc analysis of two recently published randomized controlled trials of a physician-pharmacist collaborative intervention to improve blood pressure control; one was a 9-month intervention,[21] and the other was a 6-month intervention. [22]

Original Randomized Controlled Trials

The design of these two trials has been previously published.[21, 22] Briefly, 11 university-affiliated primary care clinics in Iowa were involved in these studies. The clinics were randomized to either intervention (five clinics) or control (six clinics) groups. Patients were allocated to these groups based on the clinic randomization to avoid within-clinic or within-physician contamination. Patients in both groups had scheduled study visits with the research nurse. The studies were approved by the University of Iowa Institutional Review Board and by five local institutional review boards for the second study. All patients provided written informed consent.

Eligible patients were aged 21-85 years with primary uncontrolled hypertension who were taking up to three antihypertensive agents, with no changes to their regimen during the past 4 weeks. In the first study, patients without diabetes mellitus or chronic kidney disease were eligible if their clinic systolic blood pressure was 145-179 mm Hg or diastolic blood pressure 95-109 mm Hg.[21] Patients with diabetes or chronic kidney disease were eligible if their clinic systolic blood pressure was 135-179 mm Hg or diastolic blood pressure 85-109 mm Hg. The second study enrolled patients without diabetes or chronic kidney disease who had systolic blood pressures of 140-179 mm Hg or diastolic blood pressures of 90-109 mm Hg.[22] Patients with diabetes or chronic kidney disease were eligible if their clinic systolic blood pressure was 130-179 mm Hg or diastolic blood pressure 80-109 mm Hg.

Patients were excluded if they had previously been seen by the 24-hour blood pressure monitoring service; had a blood pressure above 180/110 mm Hg or any evidence of hypertensive emergency, stroke, or myocardial infarction in the previous 6 months; or had any of the following conditions: New York Heart Association class III or IV heart failure, unstable angina, serious renal or hepatic disease, pregnancy, poor prognosis with a life expectancy less than 3 years, or dementia or cognitive impairment.

Educational lectures were provided to physicians in all clinics by one investigator immediately before patients were enrolled. The Seventh Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-7) guidelines[23] were supplied to all physicians.

Current Study

In the current post hoc analysis, we included data from the baseline and end-of-study visits for both the 9- and 6-month studies,[21, 22] and analyzed the data based on the duration of time

the patient remained in the study. Baseline data included patient demographics, blood pressures, and the results of drug self-efficacy[7] and social support[13] questionnaires.

Assessment of Self-Efficacy, Social Support, and Drug Adherence—The self-efficacy questionnaire contains 27 items—each describing scenarios that the patient rates from 1 (not confident) to 5 (confident) concerning their perceived ability to take their antihypertensive drugs under certain common situations[19]—with a total maximum score of 135. The social support questionnaire contains nine items, answered as true or false, that asks about family and home support.[14, 20] These items are ranked as 1 or 0, with 1 indicating a positive response (and total maximum score of 9). The validated Morisky self-reported adherence scale was also administered.[24] It consists of a five-question tool, with a "yes" answer indicating nonadherence; total scores range from 0-5, with 5 indicating the least adherence. All questionnaires were verbally administered by research nurses who were available to aid patients in interpreting questions if needed.

The validity of self-reported drug adherence was confirmed in one of the two studies by measuring pill counts of all antihypertensive drugs at each study visit using the same study procedures as those used in the African American Study of Kidney Disease (AASK),[25] which was funded by the National Institutes of Health (NIH), as were our two studies. The percentage of drug doses taken correctly were calculated at baseline and at the end of each study using the procedure used in the AASK study (using their case report forms, with permission obtained from the investigators).

Blood Pressure Measurements—At each of the data collection visits, the nurse measured blood pressure 3 times using standardized techniques as performed in clinical trials.[25, 26] The first blood pressure value was not counted since the first value is often higher than subsequent readings. This blood pressure procedure is commonly used in clinical trials funded by the NIH, such as the AASK.[25] The average of the second and third blood pressure values was considered the research blood pressure. Research nurses were certified to demonstrate correct blood pressure measurement techniques. Blood pressure was considered to be at goal if it was below 140/90 mm Hg for patients without diabetes and below 130/80 for patients with diabetes or chronic kidney disease based on the JNC-7 guidelines.[4]

Pharmacist Intervention on Hypertension Management and Drug Adherence—None of the 11 clinics provided intensified hypertension management or routine drug adherence counseling by pharmacists before these studies were conducted. The hypertension intervention was implemented in all five intervention clinics specifically for the studies. Four of the six control clinics had clinical pharmacists on staff, but they were instructed to avoid counseling study patients. Patients in the control group received usual care from their primary care physician. However, pharmacists in the control clinics could continue to answer physician questions on drug therapy management (e.g., "curbside consultations") for patients (which was part of usual care in these clinics). These patients had the same structured data collection visits with the research nurse as the patients in the intervention group. All patients received a written handout explaining hypertension and lifestyle modifications provided by the National Heart, Lung, and Blood Institute.[27]

At the baseline visit, pharmacists in the intervention clinics reviewed patients' demographic factors, risk factors, coexisting conditions, smoking status, and adherence information (i.e., self-reported adherence in both studies[21, 22] plus pill counts in one study[21]) obtained by the research nurses before interviewing patients. During the interview, the pharmacists evaluated patient factors that might hinder achievement of goal blood pressure and compared the patients' current treatment with the JNC-7 guideline recommendations.[4] The pharmacists then made recommendations to physicians, mostly face-to-face, and physicians could choose to accept or reject the recommendations. In the 9-month intervention study, the pharmacists were encouraged to see patients at each scheduled research visit at baseline and at 2, 4, 6, and 8 months, with added clinic visits or telephone follow-up as needed.[21] In the 6-month study, the pharmacists were encouraged to assess drug therapy and blood pressure at baseline and at 1 month, with telephone follow-up at 3 months.[22] They were encouraged to conduct more frequent clinic visits or telephone follow-up as needed to achieve blood pressure control. If blood pressure was not controlled at the follow-up visits, the pharmacists made further recommendations to the physicians, and any changes were recorded on the case report forms. If goal blood pressure was achieved, strategies were formulated by the physician and pharmacist to maintain control.

The types of pharmacist interventions from one of the two studies have previously been published, but largely focused on intensification and individualization of the antihypertensive regimen since baseline drug adherence was generally good.[21, 28] Pharmacists also documented recommendations made to patients on lifestyle modifications. These recommendations were made on specific case report forms for the 9-month study and, thus, were only available for the intervention group.[21] In the 6-month study, however, the research nurses abstracted medical records to evaluate JNC-7 guideline[23] adherence but also recorded the types of lifestyle modifications documented in the medical record that could have been made by either the physician or pharmacist.[22]

Statistical Analysis—The numbers of specific types of recommendations (e.g., weight reduction, dietary changes, sodium restriction, increased physical activity, decrease alcohol use) and total numbers of recommendations were compared by using the χ^2 test and a two-sided Fisher exact test.

We further analyzed our data by modeling patients with low adherence versus high adherence during the study with the Genmod model. For this analysis, drug adherence was categorized as a binary variable in order to determine whether there was an association between poor adherence and self-efficacy or social support. Poor drug adherence was defined as answering yes to 3-5 of the questions on the Morisky self-reported adherence scale, whereas good drug adherence was defined as answering yes to 0-2 of the questions. Whereas this instrument had been previously divided into "low," "medium," and "high" adherence,[24] we chose to use only low and high adherence because so few of our patients would have fit into the two categories of low and medium adherence.

Statistical analyses were performed comparing within-group and between-group differences at baseline and end of study. A generalized estimating equation approach, which incorporates within-subject correlation, was used to fit the multivariate model in order to

determine the significant predictors of poor drug adherence. The SAS Genmod procedure (SAS Institute Inc., Cary, NC) with the binomial distribution and the logit link was used to fit the model. In this model, we controlled for baseline age, education, household income, insurance status, number of coexisting conditions, number of comorbidities, number of antihypertensive drugs, systolic blood pressure, number of all clinic visits, and whether patients were enrolled in the control or intervention group. Significant predictors were determined by using the Wald statistic. All analyses were performed using SAS, version 9.1.3 (SAS Institute Inc.).

Results

A total of 584 patients were enrolled in the two studies; 296 patients were in the intervention group (101 patients in the 9-mo study, 195 in the 6-mo study), and 288 patients were in the control group (78 in the 9-mo study, 210 in the 6-mo study).[21, 22] Patient demographic and blood pressure control data are summarized in Table 1. Patients in the control group were significantly more likely to have a higher number of comorbid conditions as well as a household income less than $25,000 ($p<0.0001$). In addition, a higher proportion of patients in the intervention group were married ($p=0.0004$). The intervention group had a higher baseline blood pressure than the control group ($p=0.0070$ for systolic, $p=0.0149$ for diastolic). Blood pressure improved significantly from baseline to the end of the study in both groups. Mean blood pressure was significantly lower in the intervention group (129.7/76.6 mm Hg) compared with the control group (140.8/78.9 mm Hg) at the end of the intervention ($p<0.0001$ for systolic, $p=0.032$ for diastolic).

In the 9-month intervention study, clinical pharmacists documented 441 recommendations on the case report forms concerning lifestyle modifications to patients in the intervention group.[21] Recommendations consisted of increasing activity (45%), reducing weight (27%), initiating the Dietary Approaches to Stop Hypertension (DASH) diet (22%), or other lifestyle recommendations (6%). The numbers of lifestyle recommendations in the 6-month intervention study were determined in both the control and intervention groups by medical record audit.[22] At least one form of lifestyle modification was recommended 212 times in 68% of the patients (195 patients) in the control group and 402 times in 71% (210 patients) in the intervention group ($p=0.0131$). These recommendations included losing weight (75 vs 109 times, $p=0.581$), restricting sodium (25 vs 90, $p<0.001$), increasing physical activity (85 vs 187, $p=0.0065$) and other recommendations such as other dietary changes, smoking cessation, or reducing alcohol (113 vs 178, $p>0.302$) in the control versus intervention group.

Table 2 displays the self-reported drug adherence scores at baseline and end-of-study visits. Results from the Morisky self-reported adherence questionnaire were averaged and compared between groups and within each group. These results suggested that drug adherence was good in both groups at baseline since both mean results were less than 1 on the 5-point scale. Drug adherence improved in both groups during the intervention periods, but these changes were only significant in the control group ($p=0.0053$). This latter finding was possibly due to the fact that the patients were being observed and questioned in these

clinical trials (Hawthorne effect). There was no significant difference in self-reported adherence scores between groups at baseline or end-of-study visits.

We evaluated the validity of self-reported adherence by measuring pill counts in 179 of the patients from the 9-month intervention study.[21] At baseline, the percentage of doses taken was 71% in the intervention group and 89% in the control group ($p<0.001$). At 9 months, pill counts improved to 94% in the intervention group and 92% in the control group ($p=0.369$). These data mirror the self-reported adherence scores and support the reliability of the self-reported results. The reason for the lower adherence scores in the intervention group at baseline is not apparent.

Table 3 shows the social support and self-efficacy scores at baseline and end of study. Social support was lower in the control group than in the intervention group at both time points ($p<0.02$, baseline comparison; $p<0.0002$, end-of-study comparison). Social support ($p<0.04$, baseline vs end of study) and self-efficacy ($p<0.05$, baseline vs end of study) improved significantly in the intervention group but not in the control group. These findings might suggest that the intervention resulted in a modest improvement in both social support and self-efficacy that were not seen in the control group. We conducted an intent-to-treat sensitivity analysis to address whether dropouts affected the results. There were 45 (15.6%) dropouts in the control group and 46 (15.5%) in the intervention group. If an end-of-study data point was missing, the baseline score was used for the missing variable. The results were not significantly affected by patients who withdrew from the study.

Table 4 displays the log odds of the probability of low adherence versus high adherence with either self-efficacy or social support, while adjusting for the time that patients received the intervention (6 or 9 mo). Patients with higher self-efficacy were less likely to have low adherence (odds ratio [OR] 0.946, $p<0.0001$). Social support had a similar trend, but the results were not significant (OR 0.895, $p=0.0765$). We also found that patients in the 9-month study were less likely to have low adherence (OR 0.921, $p=0.0072$) than those in the 6-month study, regardless of whether they were in the control or intervention group. These findings suggest that increased duration of study participation may have led to better adherence since this occurred in both the control and intervention groups. There were similar time trends for better self-efficacy, but this did not reach statistical significance (OR 0.940, $p=0.0667$).

Table 5 shows the multivariate Genmod model of log odds of probability of low adherence. The strength of these predictors was measured in terms of OR and 95% confidence intervals, controlling for all covariates in the analyses. As age increased, patients were less likely to have low adherence ($p<0.0001$) when controlling for covariates in the model. These results are supported by many other studies that found that older patients are more likely to adhere to their drug regimens than younger patients.[11, 29, 30] Patients with higher self-efficacy were less likely to be in the low-adherence group ($p<0.0001$) when adjusting for other covariates. These findings are also supported by other literature that shows that patients with high self-efficacy (i.e., confident that they can take their drugs in common situations) are more likely to have higher drug adherence.[12, 19]

Discussion

This post-hoc analysis found that social support and self-efficacy improved on the basis of the time patients participated in the two clinical studies. These findings suggest that these variables improved perhaps due to participation in the trial (Hawthorne effect) rather than due to any effect of the intervention. The fact that social support, self-efficacy, and drug adherence were high at baseline may have influenced these findings. This study targeted patients with poor blood pressure control, and the largest barrier in these patients was suboptimal drug regimens, not poor drug adherence. Future studies should examine these relationships in a population of patients with documented poor adherence. Our findings also have important implications for researchers. We observed improved drug adherence with time, regardless of whether the patient was in the control or intervention group. These findings suggest that the longer a patient is in a research study, the greater the effect on adherence would be. These findings also support the need for control groups for pharmacist intervention studies.

Previous studies have found that improved self-efficacy and/or social support was associated with better drug adherence.[5, 7, 12-14] We hypothesized that the pharmacist intervention would influence patient behavior by improving self-efficacy and/or social support, especially for those with low drug adherence. Building a relationship with patients and providing education that is individually tailored to affect behavior could improve self-efficacy and possibly social support, thereby promoting drug adherence. The pharmacists also might have addressed patients' fears regarding their condition and drug regimen, reinforced the seriousness of the patients' condition, and helped patients to integrate drug regimens into their daily life. The relatively high self-efficacy and social support, as well as self-reported adherence, somewhat limited our ability to confirm this hypothesis.

Given that adherence to an antihypertensive regimen is a key aspect in controlling blood pressure, it is important to evaluate factors that influence adherence, identify predictors of adherence, and accurately monitor and quantify adherence. As adherence to antihypertensive regimens is often poor, finding ways to improve adherence is important. This study suggests that study procedures may also influence patient perceptions of their self-efficacy and perhaps social support, and these procedures and perceptions may improve drug adherence. These findings also demonstrate the importance of robust study designs with control groups to help evaluate the influence of any intervention and to evaluate the components that may influence the outcomes of an intervention.

Previous studies, including one in an African-American population, have shown that patients with higher self-efficacy scores have better adherence.[7] The self-efficacy questionnaire used in our study was designed to elicit responses indicative of the patient's willingness or confidence in their ability to take their drugs under various circumstances. Those circumstances, which included whether the drug was too expensive, was hard to swallow, was difficult to take if the patient was at work or on vacation, or might decrease the patient's interest in sex, may affect the ability of a patient to adhere to their regimen. Self-efficacy scores were high overall in our study (122-124 in both groups out of a possible 135) without a significant difference between groups. We considered values over 100 to be high. Whereas

the modest improvement in self-efficacy in the intervention group was statistically significant, its clinical relevance is questionable.

The other main focus of our study was to determine the association between social support and adherence. Items on the social support questionnaire were designed to assess the nature of the family and relationships in the home. We hypothesized that although the increased interaction with the pharmacist would be unlikely to have an effect on home life, it could increase social support by involving the family and by educating the patient regarding treatment decisions and options. Again, as with the self-efficacy scores, the baseline social support scores were relatively high and remained high throughout the trial (7.4-7.9 for both groups out of a possible 9). We considered values above 7 to be high. The intervention group, of whom a greater proportion were married and had a higher income, had higher social support at baseline than the control group. Even so, the intervention group experienced a small, statistically significant improvement whereas the control group's social support did not change significantly. This improvement in social support could also have contributed to better adherence, but again, these modest changes probably are not clinically relevant.

Modeling the patients into low and high adherence groups was important to confirm factors that are associated with better adherence in those who started with low adherence. In this study, being older and having higher self-efficacy were significant predictors of better self-reported adherence during the study. Younger patients and those with lower self-efficacy may benefit the most from targeted adherence interventions, as was also found in another study from a largely African-American population.[31] Reasons that older patients seem to have better adherence are that they take their condition more seriously, they have a less hectic or more regular schedule, and they have developed a routine for taking their drugs.[11] Providing patients with education about their drugs and the benefits of being adherent; recommending more frequent clinic visits, leading to a stronger patient-provider relationship; or providing aids to help a patient remember to take drugs are ways pharmacists can help to improve self-efficacy and ultimately adherence. Other studies have shown that adherence can be improved by increased pharmacist-physician interaction.[32] It has also been shown that multidisciplinary teams, notably pharmacist-physician teams, can both increase adherence and improve blood pressure control.[21, 33] Patients are able to form a better relationship with their pharmacist and physician and better understand their treatment. These interactions would, in theory, improve self-efficacy, thereby improving adherence and blood pressure control.

The improvement in adherence in the intervention group was not significant since adherence at baseline was generally good. The control group did have significant improvement in adherence yet did not achieve the level of improvement in blood pressure control as that seen in the intervention group. This suggests that adherence was not the main causative variable that was responsible for the blood pressure improvement in these two trials.[21, 22] Our findings are consistent with other studies that have shown that poor drug adherence is the source of poor blood pressure control in only 15-20% of patients.[34, 35]

Blood pressures in both groups improved significantly during the trials but were significantly better in the intervention group than the control group.[21, 22] We previously demonstrated that physician knowledge either did not change or deteriorated from baseline to the end of one[21] of the studies, suggesting that physician knowledge did not influence the blood pressure results.[36] Both of these studies concluded that the pharmacist intervention had a significantly greater effect on mean blood pressure and blood pressure control rates compared with the control group and that the primary mechanism of the intervention was to intensify the blood pressure regimen and overcome "clinical inertia." Dosage titrations and drug additions in the intervention group were common in the first few months, when resultant drops in blood pressures were most noticeable.[21, 22]

Limitations

One of the main limitations of this analysis was that adherence was high at baseline. The results may have been different if the intervention were targeted at a population of patients with documented poor adherence. The fact that we used only one method of measuring adherence, the Morisky self-reported adherence scale, could have affected the results. Tools to measure adherence must be valid predictors of adherence and, consequently, blood pressure control because they can influence hypertension research and clinical decision making.[37] Problems inherent with using a questionnaire may limit the accuracy of self-reporting. Although this scale has been validated, it relies heavily on patient awareness and honesty regarding missed doses.[24] However, the results of self-reported adherence were confirmed by pill counts in one[21] of the two studies used in this analysis. Pill counts were not used in the other study,[22] which enrolled two thirds of the total study patients.

Other strategies, such as pharmacy refill counts or electronic prescription vial caps (or MEMS [medication event monitoring system] caps, which record every time the lid is removed from the vial), have been used to assess adherence. These strategies have been shown to be largely in agreement in their assessments of adherence.[38] It is also important to note that for large trials that enroll many patients with multiple drugs, like those analyzed here, the MEMS caps are too expensive to be feasible. Pharmacy databases could also not be used in these studies since the patients used multiple community pharmacies for their drug therapy.

Another limitation is that social support and self-efficacy began and remained high throughout the study, further diminishing the variation of data in this analysis. In order to establish causation between increased social support or self-efficacy and better adherence, it would be important to have patients with a greater range of adherence, social support, and self-efficacy scores at baseline. Our findings could be due to selection bias since volunteers who had high self-efficacy and social support may have had better adherence. Those with poor adherence may have declined participation in the trial.

Our exclusion criteria may have influenced the results of the analysis. Patients with cognitive, renal, or hepatic dysfunction; those with class III or IV heart failure; and those with recent cardiovascular events were all excluded in both trials. This was done because the NIH, which sponsored both studies, typically requires the exclusion of high-risk individuals in these types of hypertension studies. The excluded patients may very well be those who

have had poor adherence and for whom improvements in self-efficacy or social support could have been beneficial. Future studies on adherence should attempt to enroll patients with a wider range of adherence, social support, and self-efficacy scores at baseline.

The two studies used different methods to document lifestyle modifications recommended by pharmacists. In one study, the recommendations were documented only in the intervention group.[21] In the other study, these recommendations were evaluated by medical record review, and they could have been made by either the physician or the pharmacist.[22] Thus, due to the limitations of a retrospective medical record review, the number of recommendations might have been underestimated in that study. However, both studies showed that recommendations for lifestyle modifications were frequently being made.

Finally, the durations of the two studies differed in length (9 mo and 6 mo) and were relatively short. We do not believe, however, that these factors influenced the results, which would have been more important if self-efficacy, social support, and/or adherence were low at baseline and did not increase significantly after the intervention, which was not the case in this analysis.

Conclusion

This post-hoc analysis found a modest influence of self-efficacy on drug adherence in the intervention group. Although the social support and self-efficacy scores did improve significantly in the intervention group from baseline to end of study, only the control group had significant improvement in self-reported drug adherence. Since the majority of patients began with high social support and self-efficacy scores, in addition to high drug adherence scores, these factors had less room for measurable improvement and were less likely to have had an effect on blood pressure. The fact that selfefficacy, social support, and adherence appeared to improve as a function of duration of study participation suggests that volunteering for a clinical study and being observed in the trial (Hawthorne effect) may have influenced the results. These findings have important implications for the design of intervention studies. Studies evaluating drug adherence and/or pharmacist interventions should include a control group in order to control for the Hawthorne effect and the study procedures that may influence the results.

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Table 1
Demographic and Blood Pressure Control Data

Variable	Intervention Group (n=296)	Control Group (n=288)
		No. (%) of Patients
Male	115 (38.9)	129 (44.8)
Caucasian	256 (86.5)	237 (82.3)
Married	190 (64.2)	143 (49.7)[a]
Had insurance	279 (94.3)	269 (93.4)
Education beyond high school[b]	130/289 (45.0)	118/286 (41.3)
Household income < $25,000[b]	61/293 (20.8)	128/287 (44.6)[c]
		Mean ± SD
Age (yrs)	58.2 ± 14.2	59.9 ± 13.2
No. of comorbid conditions	0.490 ± 0.75	0.774 ± 0.94[d]
No. of antihypertensive drugs		
Baseline	1.77 ±0.95	1.86 ± 0.92
End of study	2.39 ± 0.97	2.20 ± 1.03
Blood pressure		
Systolic		
Baseline	153.3 ± 11.9	150.5 ± 12.9[e]
End of study	129.7 ± 14.2	140.8 ±19.5[f]
Diastolic		
Baseline	86.5 ± 11.9	84.1 ± 12.0[g]
End of study	76.6 ± 10.7	78.9 ± 13.4[h]

Baseline data were compared between groups unless otherwise specified. Unless otherwise indicated, differences between groups were not statistically significant.

[a] p=0.0004, χ^2 test.

[b] Data were not available for all patients.

[c] p<0.0001, χ^2 test.

[d] p<0.0001, *t* test.

[e] p=0.0070

[f] p<0.0001

[g] p=0.0149

$h_{p=0.032}$, *t* test.

Table 2

Self-Reported Drug Adherence

Adherence Score	Intervention Group (n=296)	Control Group (n=288)	p Value
Baseline	0.80 ± 1.22	0.92 ± 1.09	0.237
End of study	0.68 ± 1.14	0.67 ± 1.00	0.935
Mean ± SD change	−0.15 ± 1.21	−0.22 ± 1.14	
p value within group	0.0967	0.0053	

A lower score indicates better adherence.

Table 3

Social Support and Self-Efficacy Scores

Questionnaire	Intervention Group (n=296)	Control Group (n=288)	p Value
Social Support			
Baseline	7.72 ± 1.67	7.38 ± 1.80	<0.02
End of study	7.94 ± 1.59	7.36 ± 1.83	<0.0002
Mean change within group	0.185 ± 1.37	−0.045 ±1.65	
p value within group	<0.04	0.67	
Self-Efficacy			
Baseline	122.00 ± 15.06	121.77 ± 15.60	0.859
End of study	124.17 ± 14.50	122.80 ± 13.86	0.289
Mean change within group	1.89 ± 14.91	0.88 ± 10.70	
p value within group	<0.05	<0.21	

Table 4

Genmod Model of Low Drug Adherence with Self-Efficacy and Social Support Adjusting for Duration of Study Participation

Variable	Estimate	Odds Ratio	95%CI	p Value
Self-efficacy	−0.0552	0.946	0.932–0.961	<0.0001
Duration of study participation	−0.0617	0.940[a]	0.880–1.004	0.0667
Control vs intervention	−0.1482	0.862	0.491–1.514	0.6059
Social support	−0.1105	0.895	0.792–1.012	0.0765
Duration of study participation	−0.0828	0.921[a]	0.867–0.978	0.0072
Control vs intervention	−0.0302	0.970	0.562–1.673	0.9134

CI = confidence interval.

[a]Odds ratio for each additional month in the study as assessed at 0, 6, and 9 months.

Table 5
Multivariate Genmod Model for the Odds of Low Drug Adherence

Variable	Estimate	Odds Ratio	95%CI	p Value
Age	−0.0545	0.947[a]	0.922–0.972	<0.0001
Self-efficacy	−0.0538	0.948[b]	0.933–0.963	<0.0001

CI = confidence interval.

[a] Odds ratio for each additional year of age,

[b] Odds ratio for each additional point on the self-efficacy survey.