

## ONLINE FIRST

# A Randomized Controlled Trial of Positive-Affect Intervention and Medication Adherence in Hypertensive African Americans

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**Background:** Poor adherence explains poor blood pressure (BP) control; however African Americans suffer worse hypertension-related outcomes.

**Methods:** This randomized controlled trial evaluated whether a patient education intervention enhanced with positive-affect induction and self-affirmation (PA) was more effective than patient education (PE) alone in improving medication adherence and BP reduction among 256 hypertensive African Americans followed up in 2 primary care practices. Patients in both groups received a culturally tailored hypertension self-management workbook, a behavioral contract, and bimonthly telephone calls designed to help them overcome barriers to medication adherence. Also, patients in the PA group received small gifts and bimonthly telephone calls to help them incorporate positive thoughts into their daily routine and foster self-affirmation. The main outcome measures were medication adherence (assessed with electronic pill monitors) and within-patient change in BP from baseline to 12 months.

**Results:** The baseline characteristics were similar in both groups: the mean BP was 137/82 mm Hg; 36% of the pa-

tients had diabetes; 11% had stroke; and 3% had chronic kidney disease. Based on the intention-to-treat principle, medication adherence at 12 months was higher in the PA group than in the PE group (42% vs 36%, respectively;  $P = .049$ ). The within-group reduction in systolic BP (2.14 mm Hg vs 2.18 mm Hg;  $P = .98$ ) and diastolic BP (-1.59 mm Hg vs -0.78 mm Hg;  $P = .45$ ) for the PA group and PE group, respectively, was not significant.

**Conclusions:** A PE intervention enhanced with PA led to significantly higher medication adherence compared with PE alone in hypertensive African Americans. Future studies should assess the cost-effectiveness of integrating such interventions into primary care.

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**H**YPERTENSION DISPROPORTIONATELY affects African Americans compared with whites,<sup>1</sup> and it explains most of the racial gap in mortality.<sup>2</sup> Poor medication adherence may explain poor blood pressure (BP) control in hypertensive patients, especially African Americans.<sup>3,4</sup> The adverse effect of poor adherence on cardiovascular mortality and morbidity is well established.<sup>5,6</sup> Therefore, interventions targeted at improving medication adherence are necessary to reduce the racial gap in hypertension-related outcomes. Evidence suggests that successful interventions designed to improve medication adherence in patients with chronic diseases use a combined strategy, with the behavioral-education combination being the one most frequently used.<sup>7</sup> Similarly, interventions that involve patient activation, address their concerns about medications, are emotively supportive, and enhance patients' confidence in their abilities to over-

come barriers to adherence have demonstrated substantial improvements in patients' adherence behaviors.<sup>7</sup> The theoretical foundation of previous interventions are largely based on the social cognitive theory of human behavior, with a particular emphasis on self-efficacy.<sup>8</sup> However, despite the availability of effective adherence interventions in patients with cardiovascular diseases,<sup>7,9,10</sup> their effectiveness in primary care settings remains largely untested, especially among minority patients.

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Among hypertensive African Americans evaluated in a primary care practice, we examined whether a patient education (PE) intervention enhanced with posi-

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tive-affect induction and self-affirmation (PA) was more effective than PE alone in improving medication adherence and BP reduction. We hypothesized a greater effect of the PA intervention on medication adherence and BP reduction compared with PE alone over 12 months. Positive affect is a state of pleasurable engagement with the environment and reflects feelings of mild everyday happiness, joy, contentment, and enthusiasm.<sup>11</sup> It can be induced in several ways, including the receipt of unexpected compliments and gifts, a focus on positive thoughts, and the successful completion of small tasks.<sup>12</sup> The combination of positive-affect induction and self-affirmation is defined as one's motivation to preserve a positive image and self-integrity when one's self-identity is threatened.<sup>13</sup> It enhances the ability to overcome negative expectations by drawing on previous experiences of success.<sup>14</sup> It can be produced through the use of positive statements or memories about one's accomplishments or successes to build self-confidence.<sup>14</sup>

## METHODS

### STUDY POPULATION

Adult patients were recruited from a primary-care practice within the ambulatory care network of New York Presbyterian Hospital, New York, New York, during routine office visits. Eligibility included self-identification as African American or black, fluency in the English language, a diagnosis of hypertension, and the use of at least 1 antihypertensive medication. Eligible patients were identified via electronic medical records (EMRs) and review of clinic appointment schedules. The institutional review board of Weill Cornell Medical College, New York, New York, approved the study, and all patients provided written informed consent. Greater detail of the study methods has been provided elsewhere.<sup>15</sup>

### STUDY DESIGN

The study was a 2-arm randomized controlled trial with a 12-month follow-up.<sup>15</sup> After enrollment and baseline assessment, patients were followed up by individual telephone interviews bimonthly for 12 months.

### BASELINE ASSESSMENTS

At baseline, research assistants (RAs) confirmed each patient's eligibility, assessed their demographic status, and reviewed the EMRs for office BP readings, medication list, and comorbidity using the Charlson comorbidity index.<sup>16</sup> Also, patients were administered validated self-report measures to assess depressive symptoms,<sup>17</sup> social support,<sup>18</sup> medication adherence,<sup>19</sup> and positive and negative affect.<sup>20</sup> Each patient was then given an electronic pill monitor (Medic-eCap; Information Mediary Corp), which was used to assess adherence to prescribed antihypertensive medication. The electronic pill monitor consists of a standard prescription bottle with a microprocessor that records the date and time of cap openings. Patients taking more than 1 medication were given the choice of selecting which medication they wanted to have monitored for the duration of the study. They were required to return their monitors to the clinic for trained RAs to download the adherence data. Those who could not attend scheduled study visits were given preaddressed envelopes in which to return their pill monitors to the

study staff. Reminders were sent via telephone calls to all patients about returning their pill monitors.

### RANDOMIZATION

On completion of the baseline assessments, the study biostatistician randomly assigned patients to either the PE control group or the PA intervention group in a 1:1 ratio. Patient assignments were placed in sealed opaque envelopes. As is typical for most behavioral interventions, neither the patients nor the RAs were blinded to the intervention. The primary care providers did not know their patients' group assignments.

### TREATMENT GROUPS

#### PE Control Group

Patients in the PE control group received a culturally tailored educational workbook designed (1) to enhance patients' knowledge about hypertension, (2) to improve self-management behaviors, and (3) to support goal-setting.<sup>21</sup> On receipt of the workbook, trained RAs reviewed each chapter with the patients and then asked them to sign a behavioral contract that asked them to make a commitment to taking their medications as prescribed. Subsequent to this session, each patient received bimonthly telephone calls, during which the RAs assessed the patient's behavioral contract and confidence to take their medications as prescribed. These assessments served as the basis for reviewing and counseling the patient on perceived barriers to medication adherence.<sup>15</sup>

#### PA Intervention Group

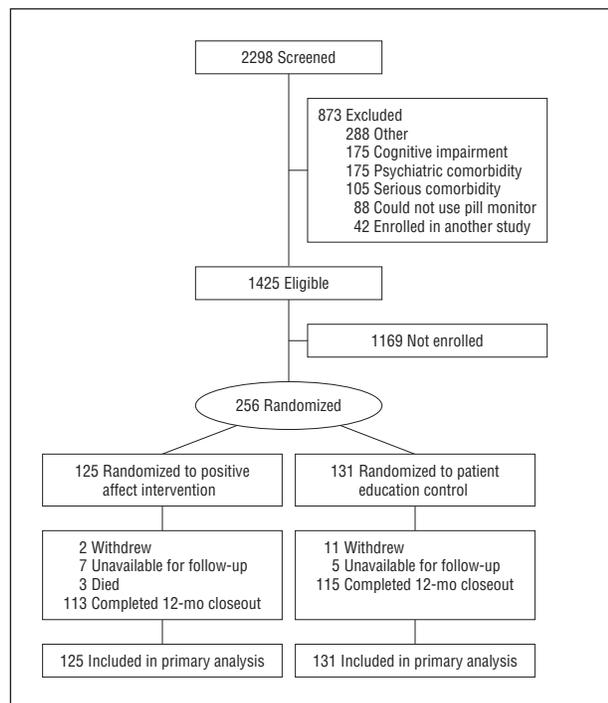
Patients randomized to the PA intervention group were given the same workbook as those in the PE group but with an additional chapter that addresses the benefits of positive moments in overcoming obstacles to medication adherence. Also, these patients received 2 forms of PA during bimonthly telephone calls. First, they were asked to identify small things in their lives that invoke positive feelings in them and were then instructed to incorporate these positive thoughts into their daily routine. The positive thoughts were further reinforced during subsequent bimonthly telephone calls. Second, the patients received unexpected small gifts mailed to them before each telephone call.<sup>22</sup> This strategy was based on the potential of the receipt of unexpected gifts to induce positive feelings.<sup>23,24</sup> For self-affirmation induction, the patients were asked to remember their core values and proud moments in their lives whenever they encounter situations that make it difficult for them to take their medications.<sup>13,14</sup>

### FOLLOW-UP ASSESSMENTS

The RAs conducted bimonthly follow-up telephone interviews with each patient for 12 months. Data collection at the final study visit was similar to that at the baseline visit.

### OUTCOMES AND MEASUREMENTS

The primary outcome was mean medication adherence at 12 months, assessed with electronic pill monitors, the accepted "gold standard" for adherence assessment.<sup>25</sup> Adherence was defined as the proportion of days in which each patient took his or her medication correctly during the 12-month study period and was known as the *scheduling adherence metric*.<sup>26</sup> For each patient, we operationalized adherence as the number of times



**Figure.** CONSORT (Consolidated Standards of Reporting Trials) diagram.

that the pill monitors recorded an opening for each day that the patient was in the study. For example, if the medication was prescribed once daily, then that patient was considered to be 100% adherent if the pill monitor records showed that the bottle had been opened once each day. For a twice-daily medication, the patient was considered 100% adherent if the pill monitor records showed that the bottle had been opened twice daily or 50% adherent if the bottle was opened only once.<sup>26,27</sup> Patients whose pill monitors showed no openings were considered nonadherent. Days during which patients visited the emergency departments or were hospitalized were deducted from the denominator for assessment of the average adherence.<sup>27</sup>

The secondary outcome was within-patient change in office BP from baseline to 12 months. Blood pressure data were extracted from patients' EMR log of office BP readings taken by nurses or certified medical assistants using standard mercury sphygmomanometers.<sup>28</sup> Blood pressure control was defined using seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure criteria of a BP greater than 130/80 mm Hg for patients with diabetes or chronic kidney disease and a BP less than 140/90 mm Hg for all other patients.<sup>29</sup> Although assessment of BP by trained RAs may be more accurate than routine office BP, we chose this approach because we sought to simulate the real-world conditions of primary care practice.

## STATISTICAL ANALYSIS

The sample size calculation was based on the difference in the mean adherence rate between the intervention and control groups at 12 months. We estimated between-group difference in medication adherence of 22%. The standard deviation for medication adherence in similar populations varies considerably and was estimated at a conservative 50%. With 90% power and 5% significance level, 109 patients were needed in each group, for a total of 218 patients, to detect the expected between-group difference in adherence. Sample size was increased by 20% to account for attrition.

Baseline clinical and demographic characteristics were compared between both groups with *t* tests or  $\chi^2$  tests, as appropriate. Because the adherence data were multimodal and highly skewed, we used a nonparametric Wilcoxon rank sum test to compare the mean adherence rate between both groups at 12 months. For the secondary outcome, we used a standard 2-sample *t* test to compare the mean within-patient change in BP from baseline to 12 months. Because the product of the expected proportions and the corresponding sample sizes were sufficiently large, normal distribution approximations are valid. All analyses were based on the intention-to-treat principle and carried out with Stata version 10 software (StataCorp).

## RESULTS

Of the 1425 eligible patients, 256 were randomized, and 87% of them completed the study (**Figure**). Patients in both groups were comparable at baseline with respect to demographic and clinical characteristics (**Table**). The mean (SD) age of the patients was 58 (12) years; most patients were female and had at least a high school education. The mean baseline BP was 137/82 mm Hg, with two-thirds of the patients having uncontrolled hypertension. Baseline psychosocial characteristics were also similar in both groups, with two-thirds of the study population reporting being nonadherent. The study population reported a relatively higher level of negative affect (about the 77th percentile for the general population) and a lower level of positive affect (about the 57th percentile for the general population).<sup>30</sup> More than 75% of the patients in both groups received at least 4 of the 6 bimonthly telephone calls. With respect to delivery of the components of the PA intervention, 96% of the patients reported using the techniques for positive-affect induction, 74% used self-affirmation induction techniques weekly, and more than 80% received their mailed gifts.

Based on the intention-to-treat principle, medication adherence at 12 months was higher in the PA group than in the PE group (42% vs 36%, respectively;  $P = .049$ ). The difference, the absolute risk reduction, was 6.25%, which yields a number needed to treat of 16. This means that about 1 in every 16 patients will benefit from the treatment. The within-group reduction in systolic BP for both groups was not statistically significant (2.14 mm Hg for the PA group vs 2.18 mm Hg for the PE group;  $P = .98$ ); similarly, the within-group reduction in diastolic BP from baseline to 12 months was  $-1.59$  mm Hg for the PA group and  $-0.78$  mm Hg for the PE group ( $P = .45$ ). Therefore, the PA intervention had a significant impact on medication adherence but not on BP reduction.

## COMMENT

In this study, we demonstrated that PA was more effective than PE alone in improving medication adherence in hypertensive African Americans. Given the transient effect of PE alone on medication adherence, the PE group was supplemented with PA to strengthen the intervention effect.

Several mechanisms may explain our findings. First, although knowledge is necessary but not sufficient for health behavior change, the addition of PA constructs to

**Table. Baseline Patient Characteristics**

Variable	Patient Education Control Group (n=131)	Patient Affect Intervention Group (n=125)	P Value
Demographic characteristics			
Age, mean (SD), y	59 (12)	57 (12)	.19
Women, %	77	82	.29
Employed, %	40	43	.33
Married, %	24	25	.64
Completed college, %	56	60	.59
Clinical characteristics			
Duration of hypertension, y	11	12	.36
Systolic BP, mean (SD), mm Hg	140 (17)	135 (19)	.05
Diastolic BP, mean (SD), mm Hg	83 (12)	81 (12)	.58
Uncontrolled hypertension, %	72	64	.14
Renal disease, %	3	4	.68
Diabetes, %	34	37	.68
Stroke, %	8	14	.12
Charlson comorbidity index, %			.12
0-1	16	30	
2-3	47	35	
>3	37	35	
Depressive symptoms score, mean <sup>a</sup>	8	8	.45
Positive affect score, mean <sup>b</sup>	34.5	35	.61
Negative affect score, mean <sup>b</sup>	18	19	.74
Social support score, mean <sup>c</sup>	75	76	.84
Perceived stress score, mean <sup>d</sup>	14	14	.65
Medication adherence score, mean <sup>e</sup>	1.2	1.0	.39
Nonadherent (self-report), % <sup>e</sup>	65	60	.83

Abbreviation: BP, blood pressure.

<sup>a</sup> Measured by the Center for Epidemiologic Studies of Depression Scale (possible score range, 0-60); higher score means more depressive symptoms.

<sup>b</sup> Affect measured by the Positive and Negative Affect Schedule (possible score range for each subscale, 10-50); higher score means more of that attribute.

<sup>c</sup> Measured by the MOS (Medical Outcomes Study) Social Support Scale (possible score range, 0-100); higher score means more support.

<sup>d</sup> Measured by the Perceived Stress Scale (possible score range, 0-40); higher score means more stress.

<sup>e</sup> Measured by the Morisky Medication Adherence Questionnaire (possible range, 0-4); higher score means less medication adherence. Patients with a score greater than 1 were categorized as nonadherent.

the PE workbook may have led to greater self-efficacy and behavioral activation of patients in the PA intervention group, thus enhancing their desire and ability to adhere to prescribed antihypertensive medications. For example, in 2 studies, a mild positive affect of the type induced in our study increased patients' perception of a connection between their effort and behavior, as well as their success and positive outcomes, leading to improved performance.<sup>11</sup> Second, the negative effect of depressive symptoms on medication adherence is well established.<sup>31</sup> Positive-affect induction may have mitigated the negative influence of depressive symptoms on medication adherence in our study. Finally, positive affect and self-affirmation are known to influence the acceptance of threatening health messages, often resulting in the adop-

tion of positive health behaviors.<sup>32</sup> For example, in a study of women at high risk for breast cancer who were presented with information on the cancer risk of alcohol intake in one group or caffeine intake in another, PA led to substantially higher ratings of risk assessment and intention to reduce alcohol intake and less biased attention to, and processing of, risk-related information regarding caffeine intake.<sup>33</sup> Similarly, in a study of sexually active adults who were presented with AIDS educational videos, self-affirmed participants purchased more condoms than control participants.<sup>34</sup> Therefore, both components of our PA intervention may have made the acceptance of the self-management approaches in the PE workbook more acceptable, with resultant improvement in medication adherence.

Several strengths of our study should be noted. First, to our knowledge, this is one of few studies that demonstrated the utility of a simple and practical behavioral intervention in improving long-term adherence in hypertensive African Americans. According to the most recent review, effective adherence interventions are often complex and labor intensive, making their translation to clinical practice impractical.<sup>9</sup> Second, adherence interventions reviewed to date suffer important limitations of short duration, lack of objective adherence measures, and small sample sizes and are often not practice based.<sup>7,9,10</sup> In contrast, our study had a relatively large sample size, was of a longer duration, used an objective measure of medication adherence, and was delivered via telephone, making its adaptation to primary care settings practical. Third, the effectiveness of practice-based approaches in improving medication adherence has remained largely untested in African Americans. Our study is one of few that tested the effect of a behavioral intervention on medication adherence in this high-risk population. Our findings are similar to those of another practice-based trial, in which we demonstrated the beneficial effects of motivational interviewing on medication adherence, with a clinically meaningful reduction in BP among hypertensive African Americans.<sup>27</sup> We should note the following important limitations of our study. The RAs were not blinded to the study. As is true for most behavioral interventions, blinding is often difficult to achieve given the nature of the proposed interventions. Finally, patients' BP readings were extracted from EMRs, which may have overestimated the levels of BP noted in our study.

In summary, our findings suggest that PE enhanced with behavioral constructs drawn from positive psychology and designed to foster PA produced significantly greater medication adherence in hypertensive African Americans than PE alone. Future studies should assess the cost-effectiveness of integrating such interventions into primary care.

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