

Culturally Appropriate Storytelling to Improve Blood Pressure

A Randomized Trial

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Background: Storytelling is emerging as a powerful tool for health promotion in vulnerable populations. However, these interventions remain largely untested in rigorous studies.

Objective: To test an interactive storytelling intervention involving DVDs.

Design: Randomized, controlled trial in which comparison patients received an attention control DVD. Separate random assignments were performed for patients with controlled or uncontrolled hypertension. (ClinicalTrials.gov registration number: NCT00875225)

Setting: An inner-city safety-net clinic in the southern United States.

Patients: 230 African Americans with hypertension.

Intervention: 3 DVDs that contained patient stories. Storytellers were drawn from the patient population.

Measurements: The outcomes were differential change in blood pressure for patients in the intervention versus the comparison group at baseline, 3 months, and 6 to 9 months.

Results: 299 African American patients were randomly assigned between December 2007 and May 2008 and 76.9% were retained

throughout the study. Most patients (71.4%) were women, and the mean age was 53.7 years. Baseline mean systolic and diastolic pressures were similar in both groups. Among patients with baseline uncontrolled hypertension, reduction favored the intervention group at 3 months for both systolic (11.21 mm Hg [95% CI, 2.51 to 19.9 mm Hg]; $P = 0.012$) and diastolic (6.43 mm Hg [CI, 1.49 to 11.45 mm Hg]; $P = 0.012$) blood pressures. Patients with baseline controlled hypertension did not significantly differ over time between study groups. Blood pressure subsequently increased for both groups, but between-group differences remained relatively constant.

Limitation: This was a single-site study with 23% loss to follow-up and only 6 months of follow-up.

Conclusion: The storytelling intervention produced substantial and significant improvements in blood pressure for patients with baseline uncontrolled hypertension.

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African Americans are 21% more likely than white persons to die of heart disease and 49% more likely to die of stroke (1). Despite many attempts to close racial and ethnic gaps in risks for cardiovascular diseases, such as hypertension, important disparities persist (2). Motivated by these findings, we sought to develop and test a novel, evidence-based, and culturally appropriate intervention to improve blood pressure control in African Americans.

Blood pressure control is complex for any patient with hypertension and requires long-term adherence to medication, diet, exercise, and medical follow-up. This complexity contributes to the widely documented poor control among patients in general (3) and African Americans in particular (4). African Americans are more likely to have hypertension, less likely to achieve control, and more likely to have end-organ damage than white persons (4). These differences in blood pressure control are partially explained by identifiable barriers, such as unhealthy diet and lack of exercise promoted by environmental factors (5), limited access to clinicians and medicine, distrust of the medical system (6, 7), and poor medication adherence (8, 9). However, interventions to overcome these barriers have had mixed results (10).

Programs that target vulnerable populations may fail for several reasons, including lack of cultural relevance. Although the resulting intervention may be conceptually

sound, the lack of cultural relevance may decrease effectiveness (5). Emerging evidence suggests that storytelling, or narrative communication, may offer a unique opportunity to promote evidence-based choices in a culturally appropriate context. Stories can help listeners make meaning of their lives (11, 12), and listeners may be influenced if they actively engage in a story, identify themselves with the storyteller, and picture themselves taking part in the action (13). Because narrative communication can break down cognitive resistance to behavior-change messages (14), we hypothesized that it would be a suitable mechanism for ad-

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Context

Appropriate management of hypertension reduces adverse health outcomes, but many patients do not adhere to treatment. A lack of understanding of the long-term consequences of this asymptomatic condition may contribute to poor adherence.

Contribution

This randomized, controlled trial assigned 299 African Americans with hypertension to receive usual care or view 3 videos that presented stories of real patients with hypertension. Among patients who had uncontrolled hypertension at baseline, those assigned to view the stories had better blood pressure control than those assigned to usual care.

Implication

Storytelling can be an effective way to teach patients about hypertension and improve blood pressure control.

—The Editors

dressing the persistent and troubling disparities in hypertension control.

We designed the Culturally Sensitive Intervention: Birmingham trial to improve hypertension control among low-income, inner-city African Americans by using an innovative storytelling intervention. According to our conceptual model (13), stories drawn from the community and told in patients' natural voices would be used to inform and inspire positive health behavior change. Using the strategies that emerged from patient interviews, we developed a narrative-based intervention delivered by interactive DVDs and tested this intervention in a randomized trial.

METHODS

We conducted a randomized, controlled trial in which 299 patients received a series of 3 DVDs, delivered at baseline, 3 months, and 6 months. Outcomes were ascertained at randomization (month 0), short-term follow-up (month 3), and end of follow-up (months 6 to 9). All patients had physician-diagnosed hypertension and were randomly assigned with equal probability to the intervention or comparison group. Patients could be enrolled at baseline with either controlled or uncontrolled hypertension; we included patients with controlled hypertension to determine whether the intervention would be useful in maintaining control.

Patients in the intervention group received DVDs that contained patient stories. The comparison group received an attention control DVD that covered health topics not related to hypertension. Our main hypothesis was that patients in the intervention group would experience more favorable changes in blood pressure than those in the com-

parison group. The institutional review boards of Cooper Green Mercy Hospital and University of Alabama at Birmingham, Birmingham, Alabama, reviewed and approved our protocol and consent procedures.

Setting and Participants

Intervention development and the subsequent trial were conducted in the Cooper Green Mercy Hospital clinics, an inner-city, safety-net health system in Birmingham, Alabama, that serves a large population of African Americans with a high burden of cardiovascular disease. Patients were recruited from the Alabama Collaboration for Cardiovascular Equality TRUST project, an observational study funded by the National Heart, Lung, and Blood Institute. We included patients aged 18 to 80 years who self-identified as African American or black; had received a diagnosis of hypertension, confirmed by medical record review; had at least 2 visits with a Cooper Green primary care physician in the past year; were not pregnant and did not have dementia, schizophrenia, bipolar illness, or any other serious acute or chronic medical comorbid condition that would interfere with study participation; and provided written informed consent.

Intervention

The intervention was delivered on an interactive DVD, rather than online or on a CD-ROM. On the basis of a national survey (15), which found that 88% of U.S. households have DVD players, this technology was thought to be more prevalent than Internet access in our sample. We began the DVD development by seeking stories from patients within the local community. Patients who represented a range of experiences (men and women, older and younger persons, and those with controlled and uncontrolled hypertension) were purposefully selected for 6 focus groups. On the basis of a carefully developed guide, moderators solicited personal experiences about hypertension, including talking with physicians; receiving medications; and strategies used to improve medication adherence, diet, and exercise. These first-stage focus groups were used to identify high-priority content and prescreen potential storytellers for subsequent videotaped interviews.

We reviewed the audiotapes and selected 14 hypertensive patients for the video production interviews, on the basis of their clarity and persuasiveness. The interviewers, using a prepared, open-ended interview guide with optional prompts based on focus group content and the Health Belief Model (16, 17), encouraged the patients to tell their stories.

We amassed 80 hours of video interview footage. Each interview was broken into discrete story units of 1 to 3 minutes each that focused on a single message. Two research assistants rated each story unit for strength and clarity of behavior-change content on the basis of the Health Belief Model (16, 17). Ratings were then used to select high-priority story segments, which were edited into a

documentary-style movie that retained the character of each storyteller.

The intervention DVDs contained 2 sections, “Storytelling” and “Learn More.” For example, the first intervention DVD featured 3 storytellers who described living with hypertension, gave lessons they had learned about how to best interact with their physicians, and offered strategies to increase medication adherence. Although common themes pervaded all of the stories, each storyteller brought a different focus and set a different tone (**Appendix Figure**, available at www.annals.org). The Learn More section of this DVD addressed the question, “What is blood pressure?,” and taught patients to express their concerns and questions to their physicians (**Appendix Figure**). The Learn More sections in subsequent DVDs focused on avoiding hidden sodium and getting adequate exercise. Material from the DVDs can be viewed at www.annals.org.

Random Assignment

After baseline screening and blood pressure measurement, patients were classified as having controlled or uncontrolled hypertension according to the guidelines in the Seventh Report of the Joint National Committee on the Detection, Evaluation, and Treatment of High Blood Pressure. Separate random assignments were performed for patients with controlled or uncontrolled hypertension. Patients in these subgroups were assigned in blocks of 10 to either the intervention or comparison group. The comparison group received an attention control DVD, which contained videos taken from “Healthy Habits Action Minute” (television messages produced locally in Birmingham, unrelated to hypertension), in addition to usual care. The attention control was designed to account for changes in attitudes and behavior that might result from social exposure, in which patients receive additional services and attention from study personnel. All participants watched the first DVD in the clinic. The booster DVDs were mailed to each patient’s home. Although we cannot confirm that the patients watched the DVDs, all respondents self-reported their watching patterns. Participants were allowed to choose which stories and Learn More sections they wished to watch and in what order. We tracked intervention delivery by measuring the total amount of time patients spent watching the DVD at both baseline and follow-up.

Outcomes and Follow-up

Our primary outcome was change in blood pressure, with readings taken immediately before random assignment (baseline), at short-term follow-up (month 3), and at the end of follow-up (months 6 to 9). Blood pressure was measured with an OmRON HEM907XL automated BP monitor (Omron Healthcare, Kyoto, Japan) according to protocols approved by the World Health Organization. Research assistants underwent intensive training with competency certification before collecting data. The assistants took 3 blood pressure readings, separated by 30 seconds, and lifted the patient’s arm between measurements. Before

the first reading, the patient sat quietly in a room for 5 minutes. For blood pressure end points, the last 2 readings were averaged. Patients were instructed to avoid caffeine, vigorous exercise, or smoking for 30 minutes before measurement. The CARDIA (Coronary Artery Risk Development in Young Adults) Web site (www.cardia.dopm.uab.edu) provides our entire, detailed protocol.

In-person and telephone interviews were also conducted, using computer-assisted technology, to collect patient demographic characteristics, current medications, and measures of intervention engagement. Comorbid conditions were ascertained from a review of medical records before study enrollment.

Statistical Analysis

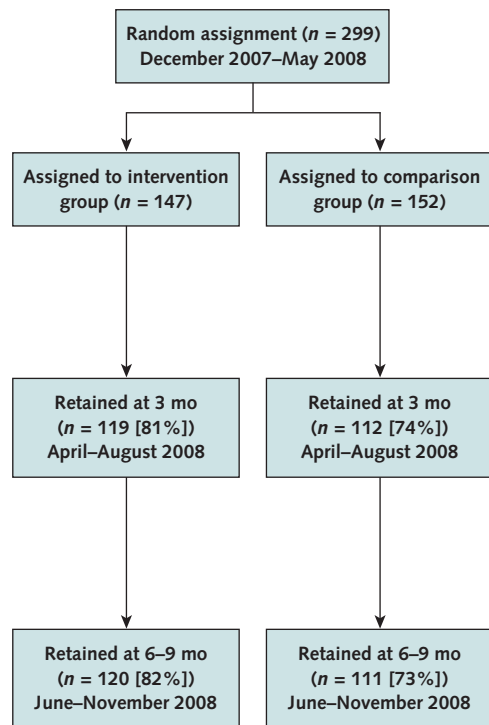
We compared baseline patient characteristics by study group to characterize the patient sample and examine the adequacy of randomization. Because of the stratified randomization scheme, separate analyses were conducted for patients with baseline controlled or uncontrolled hypertension in addition to the overall intention-to-treat analysis.

To test our main study hypothesis, we used a segmented longitudinal data analysis. Random-effects models accounted for repeated outcome measurements (systolic and diastolic blood pressures) being nested within patients. The study was divided into 2 distinct periods, from random assignment (baseline) to follow-up at 3 months and from follow-up at 3 months to follow-up at 6 to 9 months. Our models used a fixed effect for the intervention versus the comparison group, 2 fixed effects for time, 2 group–time interactions, and a random intercept that reflected the clustering of observations with patients. The regression coefficients were estimated by using a generalized least-squares algorithm, an approach that assumes data are missing at random.

The group variable was coded as 1 (intervention) or 0 (comparison). The first time variable was coded as 0 for baseline, actual calendar time for 3-month follow-up, and 0 for 6- to 9-month follow-up. The second time variable was coded as 0 for baseline, 0 for 3-month follow-up, and actual calendar time for 6- to 9-month follow-up. Separate group–time interactions were created for each period.

For these parameters, the group coefficient represented baseline differences for the intervention versus the comparison group, the first time variable represented change in the comparison group over the first period (baseline to 3 months), and the second time variable represented change in the comparison group over the entire study period (baseline to 6 to 9 months). The group–time interactions captured the main intervention effect. The first interaction represented the change over time for the intervention versus the comparison group during the first period, whereas the second interaction represented the change over time from baseline to the end of follow-up, with positive values favoring the intervention group in both cases. The main hypothesis testing was conducted on an intention-to-treat

Figure 1. Study flow diagram.



basis. The overall analyses and those stratified by baseline blood pressure control group were all performed by using Stata, version 11.1 (StataCorp, College Station, Texas).

As a secondary analysis, we examined age-related differences in systolic blood pressure response to the intervention at 3 months in patients 65 years or older versus those younger than 65 years. Longitudinal models were estimated in the same manner as for testing the main hypothesis, with interaction terms that allowed different responses by age category. These multivariate models were used to predict differential change over time in systolic blood pressure from baseline to 3 months for older versus younger patients.

Because random-effects models assume that data are missing at random, this type of analysis is vulnerable to bias from loss to follow-up. The **Appendix** (available at www.annals.org) describes our 3 main approaches to examining the potential effect of loss to follow-up.

Role of the Funding Source

This work was performed as part of Finding Answers: Disparities Research for Change, a national program of the Robert Wood Johnson Foundation, with direction and technical assistance provided by The University of Chicago. The funding source approved the study design but was not involved in the trial execution, analyses, or production of this report. In addition, Dr. Houston was supported by a Veterans Affairs Hypertension Stories grant

and Dr. Allison by the Agency for Healthcare Research and Quality Storyguides project during manuscript preparation. These agencies were also not involved in any phase of the study.

RESULTS

We randomly assigned 299 African American patients and retained 230 (76.9%) for both short-term and end-of-study follow-up (**Figure 1**). The mean elapsed time from random assignment was 3.6 months (SD, 1.9) for the 3-month follow-up and 7.8 months (SD, 2.3) for the final follow-up. Most patients (71.4%) were women, and the mean age was 53.7 years. Only 16.1% reported annual household incomes of at least \$16 000. In general, between-group differences in baseline characteristics were small (**Table 1**). At baseline, mean systolic blood pressure was 133 mm Hg (SD, 22) for the comparison group and 133 mm Hg (SD, 24) for the intervention group. Mean diastolic blood pressure at baseline was also similar in both groups.

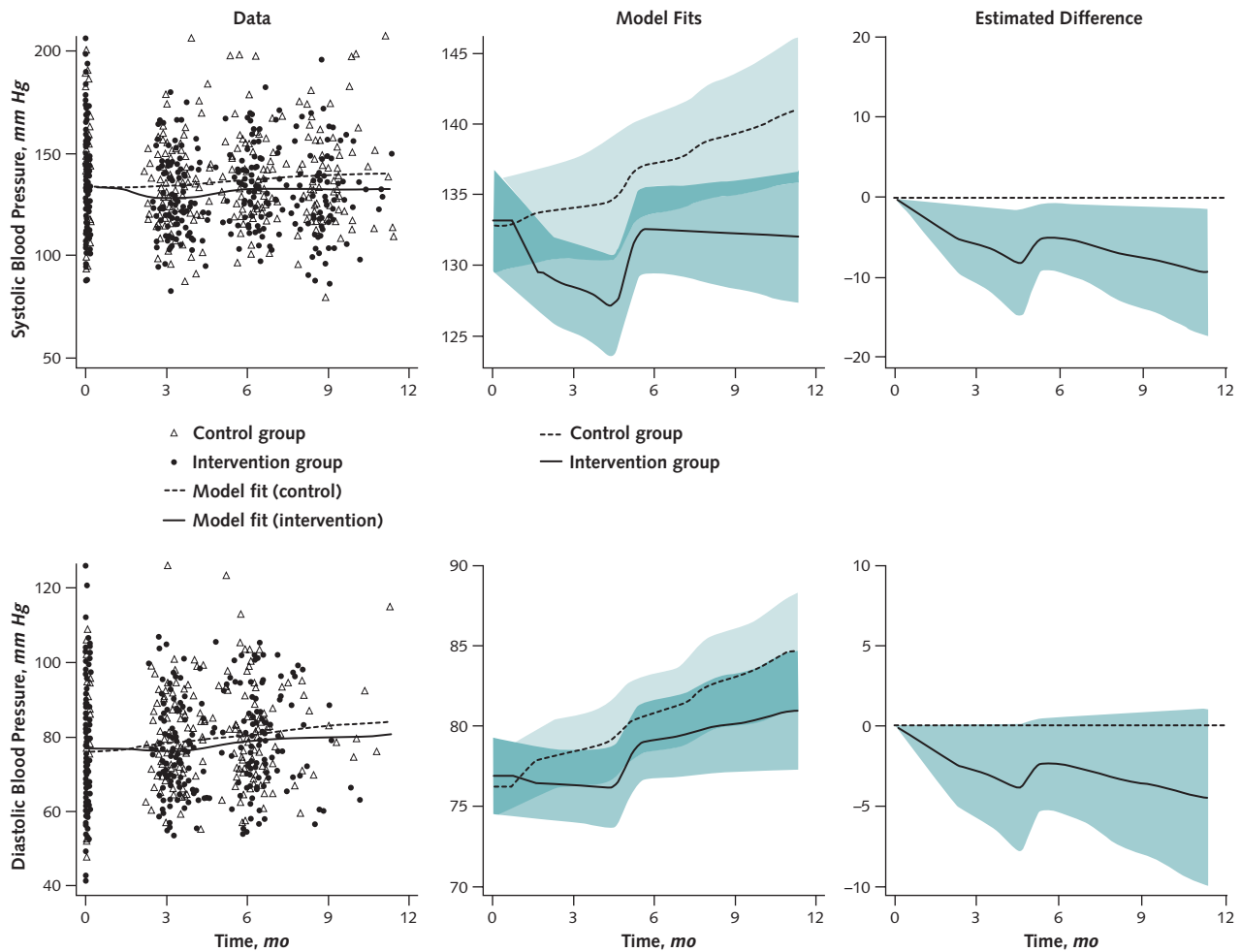
Our longitudinal data analyses estimated differential change over time for the intervention versus the comparison group (**Figure 2**). Although significant changes were associated with the intervention within the overall study population (**Figure 2, right**), these changes were driven by the patients with uncontrolled hypertension (**Tables 2 and 3**). Patients with baseline controlled hypertension experienced no signifi-

Table 1. Baseline Characteristics of Study Patients, by Group Assignment

Characteristic	Intervention Group (n = 147)	Comparison Group (n = 152)
Sex, n (%)		
Female	105 (71.43)	107 (71.33)
Male	42 (28.57)	43 (28.67)
Mean age (SD), y	53.20 (9.55)	54.14 (8.81)
Education, n (%)		
Less than high school	27 (18.37)	22 (14.67)
High school	26 (17.69)	20 (13.33)
Some college	81 (55.10)	94 (62.67)
College degree	13 (8.84)	14 (9.33)
Annual household income, n (%)		
<\$5000	41 (29.71)	37 (26.24)
\$5000–\$11 999	48 (34.78)	59 (41.84)
\$12 000–\$15 999	27 (19.57)	22 (15.60)
≥\$16 000	22 (15.94)	23 (16.31)
Comorbid conditions, n (%)		
Diabetes mellitus	57 (38.78)	68 (45.33)
Chronic kidney disease	22 (14.97)	26 (17.33)
Heart failure	5 (3.55)	9 (6.16)
Mean classes of hypertension medication per patient, n*	1.62	1.41

* Eligible classes included calcium-channel blockers, β -blockers, hydrochlorothiazide, angiotensin-converting enzyme inhibitors, centrally acting agents, and α -blockers.

Figure 2. Unadjusted data points, model fits, and estimated differences over time in systolic and diastolic blood pressures.



Left. Unadjusted data points and model fit curves for systolic and diastolic blood pressures in the intervention and control groups over time. Middle. Smoothed model fit curves for systolic and diastolic blood pressure point estimates and 95% CIs (shaded areas) from random-effects models that compared both groups over time. Curves are displayed on a truncated scale of blood pressure to provide detail. Right. Estimated differences for point estimates and 95% CIs from group–time interactions in random-effects models that compared both groups over time. Negative deflection favors the intervention group, and the nonoverlap of the 95% CI (shaded area) with the zero difference line (dashed line) indicates statistical significance.

cant differential changes in blood pressure over time. Among patients with uncontrolled hypertension, reduction from baseline to 3 months favored the intervention group for both systolic (11.21 mm Hg [95% CI, 2.51 to 19.9 mm Hg]; $P = 0.012$) and diastolic (6.43 mm Hg [CI, 1.49 to 11.45 mm Hg]; $P = 0.012$) blood pressures. Similarly, blood pressure reduction in these patients from baseline to 6 to 9 months also favored the intervention group for systolic (6.43 mm Hg [CI, 1.41 to 11.45 mm Hg]; $P = 0.012$) and diastolic (4.22 mm Hg [CI, -1.08 to 9.53 mm Hg]; $P = 0.119$) blood pressures.

Subgroup comparisons by age were limited by the small number of patients who were 65 years or older (43 patients). These patients experienced a slightly larger advantage in blood pressure reduction than younger patients (9.78 mm Hg vs. 6.31 mm Hg), but the differential response was not statistically significant (3.19 mm Hg [CI, -16.29 to 22.68 mm Hg]).

We also examined intervention delivery and engagement. All patients in the intervention group who responded confirmed watching at least 1 video segment from each of the 3 DVDs. These patients spent an average of 87.5 minutes (SD, 29.0) watching the intervention DVDs over the entire study. Viewing patterns had no relationship with changes in blood pressure.

Finally, we examined loss to follow-up (Appendix). In aggregate, our findings suggest that loss to follow-up did not heavily bias the main study findings.

DISCUSSION

To our knowledge, this is the first randomized trial of a culturally sensitive storytelling intervention for hypertensive African Americans. In a sample of 299 randomly assigned patients, we found that differences in blood pressure

Table 2. Mean Systolic and Diastolic Blood Pressures, by Subgroup, Ascertainment Time, and Hypertension Control Status at Baseline*

Subgroup and Measure	Baseline	3 Months	6–9 Months
All patients			
Patients, <i>n</i>	299	231	231
Systolic blood pressure, <i>mm Hg</i>			
Comparison	132.80	134.12	138.42
Intervention	133.18	128.03	132.38
Diastolic blood pressure, <i>mm Hg</i>			
Comparison	76.19	78.56	81.27
Intervention	76.89	76.21	79.30
Controlled hypertension at baseline			
Patients, <i>n</i>	172	136	138
Systolic blood pressure, <i>mm Hg</i>			
Comparison	120.37	125.56	130.43
Intervention	117.63	121.70	127.21
Diastolic blood pressure, <i>mm Hg</i>			
Comparison	70.89	75.17	78.31
Intervention	69.05	73.52	75.59
Uncontrolled hypertension at baseline†			
Patients, <i>n</i>	123	93	89
Systolic blood pressure, <i>mm Hg</i>			
Comparison	153.06	147.16	149.84
Intervention	152.35	135.24	137.19
Diastolic blood pressure, <i>mm Hg</i>			
Comparison	84.92	83.96	85.70
Intervention	86.62	79.23	83.18

* Blood pressure measurements were obtained according to a protocol established by the World Health Organization. Unadjusted means were taken from longitudinal data analyses based on random-effects models that nested repeated blood pressure measurements within patients.

† Defined by the Seventh Report of the Joint National Committee on the Detection, Evaluation, and Treatment of High Blood Pressure.

favored the intervention group, and the significance of these differences was driven by the positive effect among those with uncontrolled hypertension. Patients with uncontrolled hypertension who were assigned to the intervention group experienced an 11-mm Hg greater reduction in systolic blood pressure than the comparison group. Mean-

ingful advantages were also found for diastolic pressure among patients with uncontrolled hypertension. Blood pressure subsequently increased in both groups; however, the relative advantage for the intervention group was maintained until the end of follow-up. The intervention did not increase maintenance of control among patients with controlled hypertension at baseline.

We compared our findings with those from previous pharmaceutical, nonpharmaceutical, and behavioral hypertension treatment trials. According to data from the ALLHAT (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial), chlorthalidone, amlodipine, and lisinopril decreased systolic blood pressure by between 10.5 and 12.3 mm Hg and diastolic blood pressure by between 8.6 and 9.3 mm Hg over 5 years (18). Appel and colleagues (19) reported that an 8-week intervention to improve dietary behaviors of patients with hypertension led to decreases of 5.5 mm Hg in systolic blood pressure. In a systematic review of 11 studies of behavioral interventions (20), the Cochrane collaboration found that the mean reduction in systolic blood pressure for the intervention groups was -0.57 mm Hg (CI, -1.22 to 0.08 mm Hg) compared with the control groups. Thus, our intervention produced greater changes than many behavioral interventions and performed similarly to nonpharmaceutical and pharmaceutical interventions.

Hinyard and Kreuter (21) reviewed narrative communication as a mechanism of behavior change and concluded that the evidence was limited. Narrative communication for health promotion takes many forms, including storytelling, entertainment education, and testimonials (21, 22). Storytelling can change attitudes and behavior by decreasing cognitive resistance (13). Patients can “enter” the world of the characters and become absorbed in the narrative content, rather than focusing on the embedded subtext of behavior change (23, 24). Identification with the characters is promoted by *homophily*, or perceived similarity between the characters and the patient (25).

Table 3. Change Over Time in Mean Blood Pressure for the Intervention Versus Comparison Groups

Subgroup and Measure	Baseline to 3 Months		Baseline to 6–9 Months	
	Estimated Regression Coefficient (95% CI)*	<i>P</i> Value	Estimated Regression Coefficient (95% CI)*	<i>P</i> Value
All patients				
Systolic blood pressure	6.53 (1.29 to 11.76)	0.014	6.41 (1.04 to 11.77)	0.019
Diastolic blood pressure	3.05 (−0.10 to 6.21)	0.058	2.66 (−0.60 to 5.94)	0.109
Controlled hypertension at baseline				
Systolic blood pressure	1.12 (−4.71 to 6.95)	0.71	0.44 (−5.74 to 6.63)	0.89
Diastolic blood pressure	−0.19 (−3.394 to 3.55)	0.92	0.88 (−3.10 to 4.86)	0.67
Uncontrolled hypertension at baseline				
Systolic blood pressure	11.21 (2.51 to 19.91)	0.012	11.9 (3.27 to 20.59)	0.007
Diastolic blood pressure	6.43 (1.40 to 11.45)	0.012	4.22 (−1.07 to 9.52)	0.119

* Positive differences indicate greater blood pressure reduction in the intervention group than in the comparison group. Unadjusted means and 95% CIs are from longitudinal data analyses based on random-effects models that nested repeated blood pressure measurements within patients.

Although we lack direct evidence about the mechanisms through which our intervention worked, we offer some guarded speculation. A parasocial interaction, created by the homophily between patient and storyteller, may have rendered the viewers more susceptible to behavior-change messages and suggested new ways of interacting with family and health care providers (22). In a previous work on hypertension (26), we translated patient stories into reenactments by using trained actors in a high-production quality studio. To maximize the parasocial interaction in this trial, we enhanced the realism of the current intervention by taping real patients in the actual hypertension clinic instead of using actors in a studio.

Our study has limitations. Our study patients were all from an inner-city area in the southern United States with a large African American population, and the intervention may not apply to other populations. However, even though the narrative content may not be directly relevant to other racial or ethnic groups, storytelling has universal application; many cultures have rich storytelling traditions. In addition, our findings should be easily adaptable to chronic conditions besides hypertension.

We previously noted that blood pressure increased after 3 months in both the intervention and control groups. However, the increase in blood pressure was most pronounced among those with baseline controlled hypertension, which suggests regression to the mean as a possible explanation. Regardless, this indicates a need for future interventions with more sustained power of behavior change. Although we had good retention at 6 to 9 months, adjustment for covariate imbalances introduced by dropout actually strengthened our findings.

We found that patients with uncontrolled hypertension who received a storytelling intervention with culturally sensitive messages that promoted hypertension control benefited from this intervention. Additional studies are needed to clarify the mechanisms through which storytelling works, address more long-term follow-up, and test similar interventions for different populations and conditions.

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Reproducible Research Statement: *Study protocol and statistical code:* Available from Dr. Houston (e-mail, Thomas.Houston@umassmed.edu). *Data set:* Not available.

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APPENDIX: SENSITIVITY ANALYSIS

Methods

Because random-effects models assume that data are missing at random, they are vulnerable to bias from loss to follow-up. To examine the potential effect of loss to follow-up, we used 3 main approaches.

First, we compared baseline characteristics for the patients who remained at 3 months with those of patients who were lost to follow-up; separate comparisons were made for the intervention and comparison groups (Appendix Table 1). The chi-square test was used for categorical variables and the *t* test was used for continuous variables.

Second, we accounted for loss to follow-up by using inverse probability weighting. This analysis was conducted only for change in systolic blood pressure from baseline to 3 months and only for patients with baseline uncontrolled hypertension. For these models, we captured the intervention effect as a group–time interaction. Negative interaction values indicate a greater reduction in blood pressure over time in the intervention group than in the comparison group. A logistic regression model that predicted the probability of being retained in the analysis at 3 months was used to develop the weights. Predictor variables included age, income, and blood pressure. These covariates were chosen because they were at least marginally associated with retention at 3 months (Appendix Table 1). The multivariate models were estimated by using the STATA generalized linear latent mixed module, with adaptive quadrature and robust standard

errors. This module was necessary to allow weighting to be combined with the random effects that represented the clustering of observations within patients. We ran the models with and without inverse probability weighting for systolic and diastolic blood pressures (Appendix Table 2).

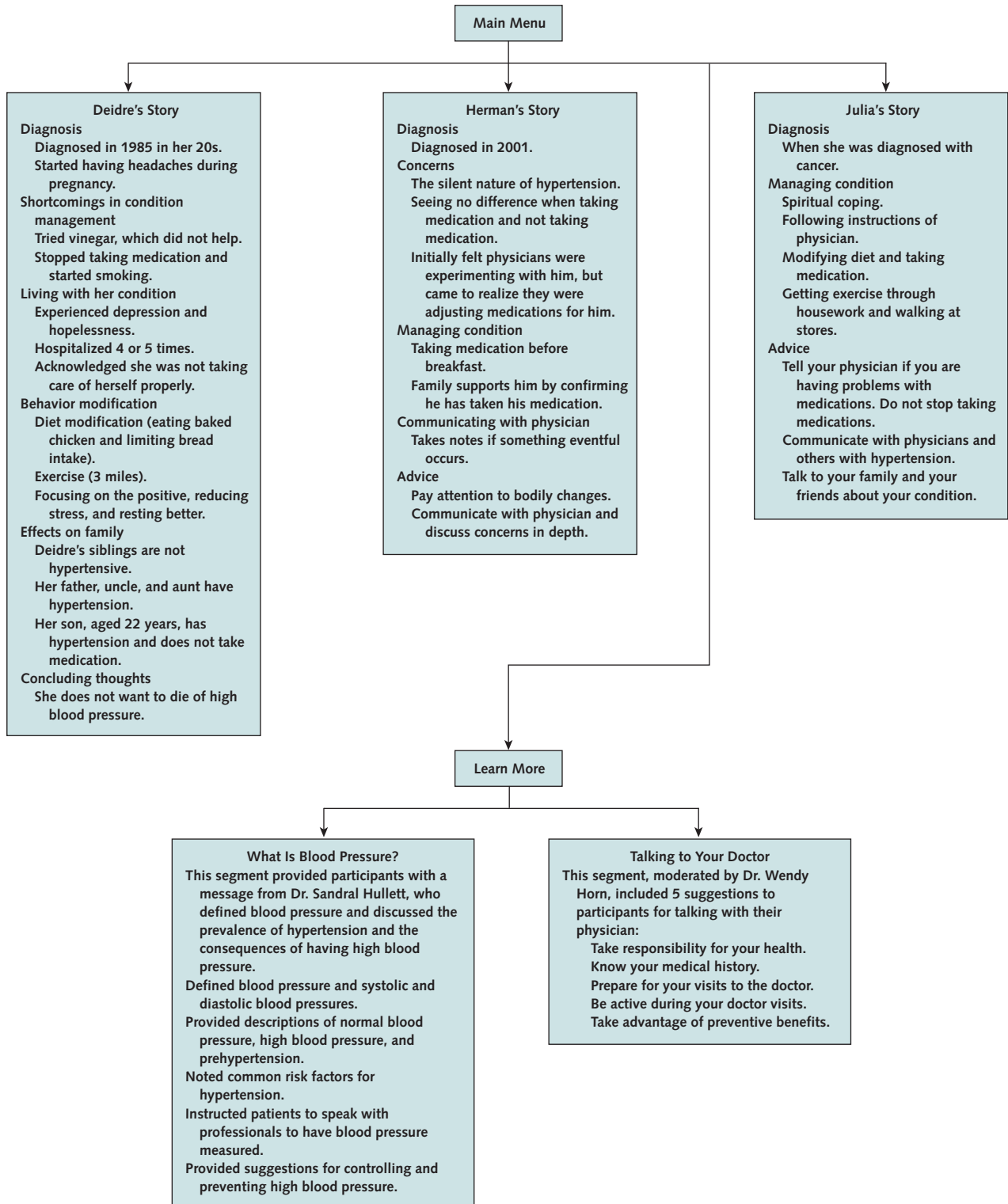
Finally, we performed a series of sensitivity analyses to determine how various assumptions about the missing data would change the intervention effect at 3 months for systolic blood pressure. The covariates for these models were structured as previously described, and analyses were similarly limited to patients with uncontrolled baseline blood pressure. Estimation was performed by using the generalized least-squares method, again accounting for the clustering of observations within patients as a random effect (Appendix Table 3). Model A treated missing blood pressure data as missing, model B carried forward the last value in the case of missing values, models C through F allowed 3-month outcomes for those with missing data to increase or decrease by 5% compared with baseline for each individual patient, and model G was titrated to illustrate a complete absence of any intervention effect.

Results

Of the 299 patients who were randomly assigned, 76.9% were available for analysis at both follow-up points. With the exception of 1 patient, all loss to follow-up occurred during the first study period. Patients were more likely to be lost to follow-up if they were younger or had lower income or higher baseline blood pressure (Appendix Table 1). These patterns were similar in both the intervention and comparison groups. Appendix Table 2 presents the main longitudinal models, weighted by the inverse probability of patients being retained in the study at 3 months. Differential change over the first study period favored the intervention group for both systolic (−10.25 mm Hg [CI, −20.04 to −0.46 mm Hg]; *P* = 0.040) and diastolic (−7.43 mm Hg [CI, −12.71 to −2.12 mm Hg]; *P* = 0.006) blood pressures. Accounting for loss to follow-up with inverse probability weighting did not significantly alter the magnitude of the main effect or the precision of its estimate.

Appendix Table 3 presents the results of sensitivity analyses in which we varied the assumptions about change in blood pressure for patients lost to follow-up. These analyses were limited to systolic blood pressure, the first study period, and patients with uncontrolled baseline blood pressure. Model A, which treated missing data as missing, yielded a mean 9.40 differential advantage over time for patients in the intervention group. These results are similar to those from the main model presented in Table 3. Model B carried forward the baseline values. Models C through F show the expected intervention effect if missing values were carried forward with increases or decreases of 5% in varying combinations for the 2 study groups. To completely negate the intervention effect, it was necessary to assume that missing systolic blood pressure values increased by 12% from baseline for the intervention group and decreased by 12% from baseline for the comparison group. In aggregate, our findings suggest that loss to follow-up did not heavily bias the main study findings.

Appendix Figure. Construct map of the first intervention DVD.



Appendix Table 1. Baseline Characteristics of Study Patients, by Missing Status at 3-Month Follow-up and Group Assignment

Characteristic	Intervention Group			Comparison Group		
	Remaining (n = 119)	Missing (n = 28)	P Value	Remaining (n = 112)	Missing (n = 40)	P Value
Sex, n (%)			0.56			0.965
Female	83 (70.34)	22 (75.86)		80 (71.43)	27 (71.05)	
Male	35 (29.66)	7 (24.11)		32 (28.57)	11 (28.95)	
Mean age (SD), y	53.76 (9.28)	50.93 (10.43)	0.167	54.99 (8.68)	51.62 (8.82)	0.044
Education, n (%)			0.91			0.36
Less than high school	21 (17.8)	6 (20.69)		16 (14.29)	6 (15.79)	
High school	20 (16.95)	6 (20.69)		12 (10.71)	8 (21.05)	
Some college	66 (55.93)	15 (51.72)		74 (66.07)	20 (52.63)	
College degree	11 (9.32)	2 (6.90)		10 (8.93)	4 (10.53)	
Annual household income, n (%)			0.140			0.007
<\$5000	29 (26.36)	12 (42.86)		20 (19.05)	17 (47.22)	
\$5000–\$11 999	38 (34.55)	10 (35.71)		46 (43.81)	13 (36.11)	
\$12 000–\$15 999	22 (20.0)	5 (17.86)		19 (18.10)	3 (8.33)	
≥\$16 000	21 (19.09)	1 (3.57)		20 (19.05)	3 (8.33)	
Comorbid conditions, n (%)						
Diabetes mellitus	44 (37.29)	13 (44.83)	0.46	47 (41.96)	21 (55.26)	0.155
Chronic kidney disease	20 (16.95)	2 (6.90)	0.174	20 (17.86)	6 (15.79)	0.77
Heart failure	3 (2.65)	2 (7.14)	0.25	7 (6.42)	2 (5.41)	0.82
Mean baseline blood pressure (SD), mm Hg*						
Systolic	132.13 (23.55)	137.02 (23.76)	0.32	131.11 (19.25)	138.15 (26.52)	0.076
Diastolic	75.79 (14.14)	81.07 (18.51)	0.093	75.16 (11.39)	79.00 (14.20)	0.091
Mean classes of hypertension medication per patient, nt	1.70 (1.56)	1.29 (1.41)	0.197	1.68 (1.63)	1.32 (1.30)	0.186

* Among all patients. Measured according to a standard protocol established by the World Health Organization.

† Eligible classes included calcium-channel blockers, β -blockers, hydrochlorothiazide, angiotensin-converting enzyme inhibitors, centrally acting agents, and α -blockers.

Appendix Table 2. Secondary Analysis With Inverse Probability Weighting to Account for Loss to Follow-up: Change in Systolic and Diastolic Blood Pressures Over Time for Patients With Uncontrolled Baseline Hypertension in the Intervention and Comparison Groups*

Main Analysis	Estimated Regression Coefficient (95% CI)	
	Systolic Blood Pressure	Diastolic Blood Pressure
Group	-0.62 (-8.07 to 6.83)	2.63 (-2.49 to 7.75)
Time	-8.69 (-15.58 to -1.80)	-0.97 (-4.38 to 2.44)
Group-time	-10.25 (-20.04 to -0.46)	-7.43 (-12.72 to -2.16)

* From longitudinal analysis. Repeated outcome measurements (systolic and diastolic blood pressures) were nested within patients. Group was coded as 1 for intervention and 0 for comparison. Time was coded as 0 for baseline and 1 for 3-month follow-up. Coefficients were estimated by generalized linear mixed models with robust SEs and adaptive quadrature. Random effects accounted for clustering of repeated observations within patients. Each patient was weighted by the inverse probability of remaining in the sample at 3 months.

Appendix Table 3. Sensitivity Analysis Based on Assumptions About Blood Pressure Change for Patients Lost to Follow-up: Differential Change for Intervention Versus Comparison Groups From Baseline to 3 Months*

Model	Assumption†		Estimated Regression Coefficient (95% CI)‡
	Intervention Group	Comparison Group	
A	Treated as missing	Treated as missing	-9.40 (-18.63 to -0.18)
B	Same as baseline	Same as baseline	-9.76 (-17.11 to -2.41)
C	5% increase	5% increase	-10.19 (-17.91 to -2.47)
D	5% decrease	5% decrease	-9.33 (-16.51 to -2.15)
E	5% increase	5% decrease	-5.84 (-13.40 to 1.73)
F	5% decrease	5% increase	-13.69 (-21.03 to -6.34)
G	12% increase	12% decrease	0.00 (-8.23 to 8.23)

* From longitudinal analysis. Repeated outcome measurement (systolic blood pressure) was nested within patients. Group was coded as 1 for intervention and 0 for comparison. Time 1 was coded as 0 for baseline and 1 for 3-month follow-up. Main intervention effect reflected in group-time interaction. Coefficients were estimated by generalized least-squares random-effects models that accounted for clustering of repeated observations over time in patients.

† Assumptions made about blood pressure values at 3 months for patients with missing data. Percentages refer to change relative to the individual patient's baseline reading.

‡ Estimated coefficient for main intervention effect at 3 months, represented by group-time interaction.