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Medication Adherence Among Rural, Low-Income Hypertensive Adults: A Randomized Trial of a Multimedia Community-Based Intervention

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Abstract

Purpose—Examine the effectiveness of a community-based, multimedia intervention on medication adherence among hypertensive adults.

Design—Randomized controlled trial.

Setting—Rural south Alabama.

Subjects—Low-income adults (N = 434) receiving medication at no charge from a public health department or a Federally Qualified Health Center.

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Intervention—Both interventions were home-based and delivered via computer by a community health advisor. The adherence promotion (AP) intervention focused on theoretical variables related to adherence (e.g., barriers, decisional balance, and role models). The cancer control condition received general cancer information.

Measures—Adherence was assessed by pill count. Other adherence-related variables, including barriers, self-efficacy, depression, and sociodemographic variables, were collected via a telephone survey.

Analysis—Chi-square analysis tested the hypothesis that a greater proportion of participants in the AP intervention are $\geq 80\%$ adherent compared to the control group. General linear modeling examined adherence as a continuous variable.

Results—Participants receiving the intervention did not differ from individuals in the control group (51 % vs. 49% adherent, respectively; $p = .67$). Clinic type predicted adherence ($p < .0001$), as did forgetting to take medications ($p = .01$) and difficulty getting to the clinic to obtain medications ($p < .001$).

Conclusions—Multilevel interventions that focus on individual behavior and community-level targets (e.g., how health care is accessed and delivered) may be needed to improve medication adherence among low-income rural residents. (*Am J Health Promot* 2011;25 [6]:372–378.)

Keywords

Rural Health; Hypertension; Behavioral Interventions; Low-income Populations; Community Health Advisors; Prevention Research. Manuscript format: research; Research purpose: intervention testing; Study design: randomized trial; Outcome measure: behavioral; Setting: local community; Health focus: medical self-care; Strategy: behavior change; Target population age: adults; Target population circumstances: income level; geographic location; race/ethnicity

PURPOSE

High blood pressure affects an estimated 73,600,000 Americans.¹ Because it is the most common cardiovascular risk factor, hypertension control is a public health priority. Although controlling high blood pressure is an important goal among varying demographic groups, it is of particular importance for minority rural residents. Rural black residents, for example, have worse blood pressure control compared to rural and urban whites.²

Medication adherence is an important component of successful hypertension management. In this paper we describe the Hypertension and Adherence in Rural Practice (HARP) trial, a community-based intervention designed to improve medication adherence among low-income, primarily black hypertensive adults. HARP integrated the Community Health Advisor (CHA) model with a computer-based intervention. The CHA model engages community residents who are considered “natural helpers” among their peers. CHAs share in the cultural aspects of the community and are familiar with local resources and health concerns. As such, involvement of CHAs in the research process capitalizes upon existing social support networks and can increase the relevance of the intervention for community residents. CHA interventions have successfully promoted cardiovascular risk reduction behaviors and affected cardiovascular-related health outcomes.^{3–5} High-tech computer-based interventions have also emerged as an effective approach to increasing health knowledge, health-related skills, and health outcomes.⁶ Computer-based interventions typically deliver interventions using predefined algorithms to tailor the intervention in response to participant characteristics and/or participant responses. As with CHA-based programs, computer-based interventions have been effective in addressing cardiovascular risk reduction.^{7–9}

Little is known, however, of the potential benefit of combining both approaches. Although potentially effective, high-tech interventions may not reflect the cultural considerations of the community and may be less accepted by community residents. Although CHA interventions address community considerations, few studies designed to address cardiovascular health and health behaviors using CHAs have been guided by theoretical frameworks,³ potentially limiting the range and impact of these interventions. Building on the respective strengths of both approaches, our innovative study integrates the CHA model with a theory-based computer intervention and tests its impact on medication adherence. In this randomized controlled trial, we hypothesized that the proportion of patients in the adherence promotion (AP) intervention taking at least 80% of prescribed doses by pill count would be larger than that of patients in the control.

METHODS

Design

After obtaining informed consent and completing the baseline assessment, participants were assigned to one of two conditions using a permuted block randomization algorithm. The AP arm was tailored to each participant using a computer algorithm. This program provided a behavioral intervention designed to enhance hypertension medication adherence (N = 221). The control arm provided general cancer information (N = 213). Both arms were delivered via laptop computers and consisted of four home visits by a trained HARP CHA over a 6-month period. The three CHAs were residents of the rural counties, with sociodemographic characteristics similar to those of the study participants, and all had previous experience conducting health promotion activities within their community. In both conditions, CHAs were randomly assigned to study participants. The study was approved by the University Institutional Review Board.

Sample

The HARP trial was conducted in two bordering rural counties in Alabama that are part of the Black Belt of Alabama, so named because of the color of the soil that made it a historical center of agricultural production. Today, the area is marked by extreme poverty. Because both counties (Wilcox and Lowndes) have similar demographic characteristics,¹⁰ only one will be described. Wilcox, a sparsely populated county with 12,911 residents in 2006,¹¹ is predominantly black (72.6% classified black or other) and poor. In 2004, over 30% of county residents lived below the federal poverty level, almost twice the state's rate.¹⁰ In 2006, deaths due to heart disease occurred at a rate of 348.5 per 100,000 in Wilcox County¹¹ compared to 270.4 for Alabama.

Recruitment occurred in community clinics (an Alabama Department of Public Health [ADPH] clinic and a Federally Qualified Health Center [FQHC]) that provided hypertension medications free of charge to individuals who met poverty guidelines. The ADPH clinic provided prescribed medications at no cost from its available sources of medicine. The FQHC provided hypertension medications for indigent patients through the pharmaceutical companies' patient assistance plans. During the conduct of the study, implementation of Medicare D occurred, requiring the FQHC clinic staff to assist patients in matching affordable Medicare Part D plans with medications offered by the patient assistance plans.

Other study eligibility criteria included (1) having a prescription for the treatment of hypertension from a health care provider, and (2) an age of 19 years or older. A total of 534 patients with hypertension were invited to participate. Twenty-seven declined. 28 could not

be located to complete the consent process, 44 did not complete the baseline survey, and 1 person was deemed ineligible. Thus, the final sample included 434 participants.

Measures

Medication adherence was assessed by pill count, conducted by registered nurses (RNs) at the ADPH clinic and by a CHA trained by ADPH RNs at the FQHC. Counts were obtained when participants visited the clinic to obtain hypertension medication refills. We required participants to bring their pill bottles and any remaining pills to the visit in order to receive a full refill, which would give the patient a 90-day supply. ADPH participants who failed to bring their medications to the visit were given a 1-week supply, after which they would return to the clinic to have pills counted and the remaining pills in their prescription dispensed (it was not possible to have this protocol implemented at the FQHC; when pill counts could not be completed at the clinic, the CHA completed pill counts at the participant's home). The information recorded for returned pills included the number returned, the medication name, and the strength and dosing information. In addition, the number of pills dispensed was recorded. Both the ADPH nurse and the CHA who conducted the pill count were blind to participant group assignment.

An adherence rate for the 6-month period postintervention was calculated as the number of pills taken by the participant divided by the number of pills expected to be taken according to the dosing instructions. For individuals on multiple hypertension medications, a composite adherence rate was developed as the sum of all numerators for all medications divided by the sum of all denominators. Participants were classified as: (1) "adherent" if the pill count suggested that the patient consumed at least 80% of the pills he or she was prescribed, or (2) "nonadherent" if the patient consumed less.

Sociodemographic information (gender, age, education, income, marital status, employment), health status, and adherence-related psychosocial variables¹²⁻¹⁴ were collected via a baseline telephone survey. To assess barriers to medication adherence, participants reported the frequency of (1) forgetting to take their medications; (2) being too busy to take medication; (3) difficulty taking their medication at the same time every day; and (4) difficulty getting to the clinic to fill their prescription.

The 10-item Center for Epidemiologic Studies Depression Scale short form was used to provide a measure of depressive symptoms, with the responses for each item: 1, rarely or none of the time; 2, some or a little of the time; 3, occasionally or a moderate amount of time; or 4, all of the time. Following reverse scoring as appropriate, responses were summed. A scale score of 10 or above is indicative of significant depressive symptoms.¹⁵

Sixteen questions addressed the participant's confidence for adhering to his/her prescribed regimen across situations (e.g., confidence in taking blood pressure medicine exactly as prescribed when the participant is feeling better; confidence in taking blood pressure medicine when the participant is busy).

Intervention

AP Intervention—The AP intervention was designed to improve medication adherence among hypertensive patients. The multimedia, computer-based program, created using Macromedia Authorware, used principles from social cognitive theory (SCT)^{16, 17} and the Transtheoretical Model (TTM)¹⁸ to (1) assess participants' psychosocial and behavioral risk factors relevant to adherence and (2) help participants develop and maintain behavior management skills for taking medication. As such, the intervention focused on changing individual-level behaviors such as goal setting and self monitoring.

The AP intervention was delivered via a “Cyber Nurse” and a “Video Doc,” with a CHA who served as the liaison between the computer and the participant. The “Cyber Nurse” was an audio recording of a female voice providing guidance to both the CHA and the participant throughout the program, including segueing program topics and cueing the CHA when it was time to pause to obtain participant input to standard intervention forms followed by discussion (e.g., participant hypertension-related concerns) and activities (e.g., the participant listing of adherence goals for the following week). The “Video Doc” was an African-American physician featured in a library of 50 videos ranging in length from 10 to 60 seconds. The purpose of the Video Doc was to engage, inform, and support the participant in clinical matters as determined by the assessment (e.g., explaining the relationship of participant’s high blood pressure reading with specific participant comorbidities)

The first section of the AP intervention included an assessment (medical problems, height, weight, blood pressure, medication adherence); three CHA/participant discussion points; and Video Doc tailored feedback (e.g., feedback based on patient comorbidities and health concerns). The second section included (1) Video Doc excerpts and (2) a library of Role Model Narratives. Developed for this study, the library consisted of more than 30 narratives that were based on constructs from SCT and TTM (e.g., outcome expectancies, goal setting). The narratives were from hypertensive individuals who shared their own stories about their challenges and successes with hypertension medication, and prompts were used to assess the consequences of medication nonadherence, perceived benefits for taking medication, and self-monitoring techniques.

Based on medication adherence and blood pressure measurement, in the second section of the AP intervention, the computer directed the participant down one of six branches. Each branch included clear, low-literacy video displays (Video Doc clips, Role Model narratives), two CHA/participant discussion points, and handouts used to reinforce messages. For example, participants who had uncontrolled blood pressure, were not adherent to prescribed medication, and had negative medication attitudes (e.g., believed that blood pressure medicines will not work as well if taken all the time) were directed to a branch that addressed medication attitudes. When directed by the Cyber Nurse, the CHA paused the computer to engage the participant and promote consideration of the program content and how it could be applied to his/her life with hypertension. The primary interaction was to request the participant to complete worksheets (e.g., documenting adherence-related goals for the following week or designating on a preprinted form health conditions that were of concern) and to answer questions concerning the completion of the worksheets. However, the intervention was predominantly presented by the tailored multimedia computer program.

Each of the four AP intervention sessions was followed by a single telephone contact by the CHA at 2 weeks postsession. In each of the follow-up calls, the CHA addressed the participant’s goals established during the preceding home visit to review and reinforce continued use of the tailored AP strategies presented at that visit.

Training of CHAs and Adherence to Protocol—The AP intervention employed a substantive CHA Operations Manual that also served as the training manual. The CHA training curriculum was organized around the specific skills needed to implement the intervention. CHAs became familiar with the multimedia program, learned how to take a participant’s blood pressure, and learned how to engage patients in the various intervention activities and complete the associated forms (e.g., participants set weekly adherence goals, developed strategies to remind them to take their medicines, etc.). The CHA with supervisory responsibility for the other intervention CHAs received 3 months of weekly sessions prior to another 4 months of weekly sessions attended by all CHAs. Consistent with

the principles of SCT, CHAs practiced skills (i.e., intervention delivery) through various role plays and received feedback from the other CHAs, a psychologist, and the program manager responsible for training the CHAs. The need to minimize unstructured conversation with patients was emphasized, and questions that patients were anticipated to ask were practiced in role play.

Weekly conference calls between CHAs and staff reviewed progress and discussed problems that occurred during the implementation of the intervention. Solutions for these problems were identified. Quarterly face-to-face meetings of CHAs and staff were held to assess fidelity to protocol and to address any persistent problems.

Cancer Control—In order to test the effects of the computer tailoring on hypertension control, the cancer control (CC) intervention was unrelated to hypertension or medication adherence and covered several cancer topics (e.g., overview of cancer; specific cancers, including symptoms, risk factors, and early detection methods; and cancer and lifestyle choices). Similar to the AP intervention, the CC intervention was led by a CHA, consisted of four sessions, and was delivered via computer.

Analysis

SAS (version 9.1) was used to conduct the statistical analyses. Descriptive statistics including means, standard deviations, and frequencies were calculated. A χ^2 analysis was used to test whether the proportion of patients in the AP condition taking at least 80% of prescribed doses by pill count was larger than that of patients in the CC condition. With a sample size of 426 and assuming that half of the participants in the CC condition took at least 80% of their prescribed medication, the analytical design provided 88% power to detect a treatment difference of 15% between the conditions.

Using general linear modeling (GLM), we examined adherence as a continuous outcome. Intervention group (AP or CC), clinic type (ADPH or FQHC), and the interaction of intervention and clinic type were the primary independent variables. Potential covariates (depressive symptoms, self-efficacy, barriers, education, and income) were identified through univariate analysis (variables significant at $p < .1$ were retained). Before building the general linear model, we examined the distribution of adherence rates and confirmed that its distribution did not violate the normality assumption.

RESULTS

Table 1 shows the sociodemographic and clinical characteristics of the study population. At baseline, participants randomized to the AP condition did not differ from participants randomized to CC (all p values $> .05$).

Our study hypothesis that a higher proportion of individuals in AP would be adherent compared to those in CC was not supported. In the AP arm, 51% were classified as adherent. In the CC arm, 49% were adherent to their antihypertensive medication regimen, $p = .67$.

Notably, outcome data for 96 of 434 participants were not available (e.g., information was not available to calculate adherence). To determine if individuals included in the outcome analyses ($N = 338$) were different from those excluded ($N = 96$), we conducted bivariate analyses. Overall, there was not sufficient statistical and clinical evidence to suggest that at baseline, individuals included in the outcome analyses were different from individuals with missing outcome data (data not shown).

Univariate analyses indicated that “forgetting to take medication” and “difficulty getting to the clinic for medications” were significant barriers. Thus, these variables were included in the full GLM model. Results of this model indicated that clinic type predicted adherence ($p < .0001$), as did sometimes forgetting to take one’s medication compared to never forgetting ($p = .01$), and difficulty getting to the clinic to obtain medications ($p < .001$). The interaction term (intervention X clinic) was not significant ($p > .05$; Table 2).

The finding that clinic type was associated with adherence was unexpected. We examined the impact of clinic type on medication adherence over the first 6 months of participant clinic visits (during the time of intervention delivery) and over the entire 12 months. In both analyses, clinic type was associated with adherence ($p < .0001$).

Given the persistent difference in medication adherence between ADPH and FHQC participants, we conducted analyses to determine if differences in adherence rates could be explained by differences in participant baseline characteristics. These analyses suggested that participants from the two clinic types did not differ with regard to age, depression, education, health status, or income. There were differences, however, with regard to number of medications. On average, ADPH participants were prescribed 2.21 ± 1.18 medications vs. 1.31 ± 1.29 medications prescribed to FHQC participants ($p < .0001$). Clinic type populations also differed with regard to gender. Approximately 73% of ADPH participants were female versus 55% of FHQC participants ($p < .0003$). We also examined whether the two clinics differed with regard to transportation difficulties. Compared to participants who reported that they never found it hard to get to the clinic to refill their prescriptions, participants who indicated that it was hard “most of the time” were five times more likely to be FHQC participants (odds ratio 5.06; confidence interval 1.68 to 15.27, $p = .0040$).

DISCUSSION

The present study provides new and important information. Rural, low-income, hypertensive patients with a regular source of care and access to medication at no charge continue to encounter medication adherence barriers. Our randomized controlled trial of a multimedia, community-based intervention designed to increase medication adherence in this population found no difference in medication adherence rates by intervention group. We did observe that patients sometimes forgetting to take medications, patients reporting difficulty getting to the clinic for medications, and patients receiving care at a FQHC clinic did have lower adherence rates.

The intervention’s focus on individual-level variables (e.g., building the participant’s confidence to adhere to their medication and modifying beliefs and behavior) was not sufficient to improve medication adherence in this population. In our study, difficulty getting to the clinic to obtain medication was associated with medication nonadherence, a finding similar to a study of rural residents across eight Southeastern states.¹⁹ Our study findings suggest that innovative multilevel interventions that address the contextual realities of low-income rural residents in addition to addressing patient-related factors (e.g., forgetting) are needed.

In rural communities, the geographic barrier to receiving care will continue to undermine efforts to improve the health outcomes of this vulnerable population. Although theoretically our study participants had access to care (i.e., a named provider and access to medications at no cost), residing in a medically underserved area presented an additional barrier. The FQHC clinic drew patients from multiple counties and thus a larger geographical area compared to ADPH clinics, which drew patients from a single county. The finding that participants who had the most difficulty getting to the clinic were five times as likely to be

FQHC patients as ADPH patients reflects this geographical barrier. In addition, rural counties in Alabama are typically federally designated Health Professional Shortage Areas. Although Alabama urban areas have 24.4 physicians per 10,000 residents, there are just 8.9 physicians per 10,000 residents in rural Alabama. Further, the sociodemographic profile of rural areas (namely, more older residents compared to residents in urban areas),²⁰ further challenges the system; elderly individuals are more likely to have difficulty with transportation and/or to have medical comorbidities that make it difficult to navigate the health care system. Public health initiatives that address the unique attributes of rural areas are urgently needed.

The importance of targeting variables beyond individual-level factors is further supported by our finding that clinic type was the primary influence on medication adherence. Although one might argue that the higher adherence rates observed among ADPH participants could be attributed to differences in the patient population (i.e., approximately 73% of ADPH participants were female vs. 55% of non-ADPH participants), in the literature, the relationship between gender and adherence is inconsistent.²¹⁻²³ Thus, with no differences between ADPH and FQHC participants on key variables associated with adherence, factors associated with the care models may offer insight to adherence disparities between the two groups. For example, as previously noted, Medicare Part D was implemented during the course of our study and may have disrupted patient medication adherence. Patient attrition, which was unexpectedly high, is also thought to be a product of the Medicare Part D transition. Beyond secular events, clinics that provide medications through patient assistance programs, as was the practice at the FQHC, may encounter additional challenges. The nature of these programs can introduce great variability in the medication regimens provided to patients. As such, patients may have to continually readjust their medication-taking behavior to align with new regimens, thereby making optimal medication adherence difficult. Simplification of these programs may be indicated.²⁴

This study is not without its limitations. Factors that may influence adherence to antihypertensive medication, including medical comorbidities, additional medication regimens, and cardiovascular history, were not assessed. Future studies should include a broader range of variables. Our inability to obtain pill counts on part of the sample during the follow-up period suggests that additional retention strategies are needed to encourage participation in clinic visits. Encouragingly, the participants included in the outcome analyses were not meaningfully different from the participants excluded on demographic and clinical characteristics.

Limitations notwithstanding, our study also has several strengths. First, in partnership with a rural clinic and the health department, we successfully conducted a randomized controlled trial in a population underrepresented in medication adherence intervention studies. Our ability to engage over 400 low-income, minority participants in southern rural Alabama is significant. Second, filling a gap in the literature, we developed and delivered an innovative, theory-based, multimedia, CHA cardiovascular risk reduction intervention. Third, because patients included in this study received medications at no cost to them, we were able to explore factors that influence medication adherence beyond ability to afford medications, a barrier already noted in the literature to influence medication-taking behavior.²⁵ Our primary outcome (i.e., pill count) provides an objective measure of adherence and thus further strengthens our study.

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SO WHAT? Implications for Health Promotion Practitioners and Researchers

What is already known on this topic?

While interventions for improving medication adherence have successfully enhanced adherence in the short-term, the findings for longer term chronic disease medication are discouraging. Furthermore, the majority of interventions designed to improve adherence have been conducted in urban settings, and thus, we know little of their effectiveness in low-income, rural areas.

What does this article add?

Our study is the first to integrate a community-based model with a computer-based intervention to provide theory-based tailored feedback promoting medication adherence in low-income, hypertensive, rural adults. Beyond known individual-level variables (e.g., forgetting to take medications), findings suggest that the care delivery system and difficulty travelling to retrieve medications (furnished at no cost) predict adherence.

What are the implications for health promotion practice or research?

Intervention approaches that target multiple levels (i.e., public policy, institutional, interpersonal, intrapersonal, and community factors) are likely needed to improve medication adherence in this population. Practitioners and researchers will make greater strides in adherence promotion when patient level factors are viewed in this larger context.

Table 1
 Participant Baseline Characteristics for Overall Sample and by Intervention Group for the Hypertension and Adherence in Rural Practice Study (N = 434)

	Overall Sample		Adherence Promotion*		Control*	
	No.	%	No.	%	No.	%
Clinic type						
ADPH	297	68.43	149	67.42	148	69.48
FQHC	137	31.57	72	32.58	65	30.52
Gender						
Female	293	67.51	145	65.61	148	69.48
Male	141	32.49	76	34.39	65	30.52
Race[†]						
Black	410	94.69	209	94.57	201	94.81
White or other	23	5.31	12	5.43	11	5.19
Education						
<High school	219	50.46	109	49.32	110	51.64
=High school	163	37.66	85	38.46	78	36.62
>High school	52	11.98	27	12.22	25	11.74
Income						
<\$15,000	355	81.80	180	81.45	175	82.16
≥\$15,000	79	18.20	41	18.55	38	17.84
Marital status						
Married/partner	152	35.02	76	34.39	76	35.68
Other	282	64.98	145	65.61	137	64.32
Employment status						
Employed	112	25.81	60	27.15	52	24.41
Unemployed	119	27.42	57	25.79	62	29.11
Other	203	46.77	104	47.06	99	46.48
Perceived health status						
Excellent/VG	45	10.37	27	12.22	18	8.45
Good	170	39.17	84	38.01	86	40.38

	Overall Sample		Adherence Promotion*		Control*	
	No.	%	No.	%	No.	%
Fair or poor	219	50.46	110	49.77	109	51.17
Age, y [§]	56.11	13.10	56.94	12.30	55.24	13.86
CES-D score [§]	9.75	5.19	9.55	5.40	9.95	4.95
Blood pressure [§]						
Systolic	136.37	17.05	136.78	18.37	135.95	15.59
Diastolic	81.73	10.65	81.57	10.38	81.90	10.95
No. medications [§]	1.93	1.29	2.04	1.36	1.81	1.20

[†] ADPH indicates Alabama Department of Public Health; FQHC, Federally Qualified Health Center; VG, very good; and CES-D, Center for Epidemiologic Studies Depression Scale.

[‡] One participant did not report race.

[§] Data are expressed as mean and SD.

* No significance between groups at the $p < 0.05$ level.

Table 2

Partial *F* Test for Individual Explanatory Factors Predicting Medication Adherence Operationalized as a Continuous Variable[†]

Source	Category	Estimate	DF	<i>F</i> statistic
Barrier: forgetting to take medication	All or most [‡]	0.151	2	4.93*
Reference category: never	Sometimes	-0.096*		
Barrier: difficult to get to clinic for medication	All	-0.036*	3	4.88*
Reference category: never	Most	0.097		
	Sometimes	0.009		
Intervention		-0.033	1	0.01
Clinic type	ADPH	0.210*	1	42.55*
Intervention × clinic	AP X ADPH	0.060	1	0.67

[†]Presented statistics are estimated by general linear model. ADPH indicates Alabama Department of Public Health; AP, adherence promotion.

[‡]Two categories are combined because individual cells have less than 10 cases.

* $p < 0.05$.