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Effects of a Treatment Adherence Enhancement Program on Health Literacy, Patient–Provider Relationships, and Adherence to HAART among Low-Income HIV-Positive Spanish-Speaking Latinos

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ABSTRACT

The impact of an adherence enhancement program for low income HIV-infected Spanish-speaking Latinos on health literacy, patient–provider relationships, and adherence to HAART was examined. Evaluations were conducted at baseline, 6 weeks, and 6 months for participants ($n = 85$) randomly assigned to either the intervention group or a comparison group; 69 (81%) remained in the study for the entire 6-month duration. The intervention group scored significantly better than the comparison group on 3 of 5 measures of HIV health literacy at 6 weeks and on 2 of 5 measures, at 6 months. While there was a weak trend for the intervention group to report an increase in self-efficacy of medication adherence management, baseline to 6 weeks, no other changes were significant. Perceptions of the quality of relationship and communications with their HIV-treating physicians improved both at 6 weeks ($p = 0.04$) and at 6 months ($p < 0.001$). The comparison group showed little change baseline to 6 weeks and baseline to 6 months. While there was a trend for the pilot group to report better medication adherence, these differences were not statistically significant. Further evaluation of the impact of this adherence enhancement program is needed.

INTRODUCTION

IT IS REASONABLE to presume that not all approaches to improving treatment adherence are effective for all groups. Multiple factors are associated with treatment adherence and different clusters of factors may play a more significant role in some groups more

than others. Critical factors found to be important in promoting adherence among socioeconomically vulnerable populations, such as low-income Latinos, may or may not include those important to adherence in other populations. To date, the literature does not adequately address interventions effective for groups less able to understand their disease

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and treatment. This study examined the effects of a treatment adherence enhancement program on health literacy, patient-provider relationships, and adherence to highly active antiretrovirus therapy (HAART) in a population of low income Spanish-speaking Latinos receiving antiretroviral therapy in community-based clinics. It was hypothesized that pilot intervention program participants, relative to those in a comparison group, would show improved levels of health literacy, patient-provider communications and relationships, and improved adherence at the same time periods. Furthermore, changes in both groups with respect to selected health status indicators (CD4 and viral load) were examined at baseline, 3 months, and 6 months.

Latino populations at risk for poor access and utilization of services

HIV/AIDS continues to impose a significant toll on racial/ethnic disadvantaged populations of the United States. In particular, Latinos of the United States have been disproportionately affected by HIV/AIDS. Although Latinos represented 14% of the U.S. population, they accounted for 17% of the newly reported AIDS cases in 2000.¹ In California, the percentage of new AIDS cases among Latino men in 2000 was 42% and for women, 41%.² More than a third of Latinos participating in the Los Angeles County surveillance survey 1997–2001 (38%), learned of their AIDS diagnosis within 1 month of their learning their HIV status, compared to 26% of Caucasians and 22% of African Americans. Low-income Latinos are believed to be at relatively greater risk for morbidity and mortality related to HIV/AIDS because of within-group vulnerability for access to and utilization of services among poor Latino men and women.³ These data draw concern to the fact that poor Latinos are at greater relative risk for AIDS and represent a significant population entering the health care system with prior difficulties in accessing care and utilizing services. It is reasonable to assume that existing interventions planned largely for persons familiar with the health care system, adept in navigating and accessing the services they need, and

possessing moderate to high literacy may fall short in addressing the needs of other less-prepared populations.

Studies of medication nonadherence in Latino populations

Problems in accessing care and utilizing services have implications for adherence to treatment. Adherence to antiretroviral therapies, particularly HAART, is problematic and a concern particularly among vulnerable populations. The management of medication adherence is made more complicated by the fact that multiple, sometimes overlapping factors, impact adherence.^{4,5} Fogarty and colleagues,⁵ isolating 200 separate variables summarized their review by indicating that some factors could be modified but others could not. Low health literacy and poor patient-provider relationships, factors frequently associated with nonadherence, are among those modifiable factors that can be addressed in adherence enhancement programs.

Rationale for targeting health literacy is borne out in multiple studies of the impact of poor health literacy. Kalichman and colleagues⁶ reported that poor health literacy creates barriers to fully understanding one's illness and treatments and is associated with poor adherence outcomes in persons receiving combination antiretroviral therapies. Those with lower health literacy had lower CD4 counts, higher viral loads, were less likely to be taking antiretroviral medications, reported a greater number of hospitalizations, and poorer health than those with higher levels of health literacy.⁷ These authors concluded that interventions are needed to improve medical care and health status of those with lower health literacy.

While there is ample evidence to support the finding that low health literacy is associated with poor medication adherence, data about within-group differences is not available. Non-adherence behaviors among low-income Spanish-speaking Latino populations with potentially low levels of health literacy have only recently been addressed. Studies of monolingual and bilingual Spanish-speaking patients have examined barriers to adherence; however, they have not included assessment of health literacy. Murphy and colleagues⁸ reported the re-

sults of focus group discussions with a sample of HIV-infected monolingual and bilingual Spanish-speaking patients ($n = 81$) and identified the following most frequently reported barriers to medication adherence: (1) feeling depressed or overwhelmed, (2) simply forgetting, and (3) sleeping through a dose. Furthermore, they reported that only 32% of these patients were consistently adherent to their medication regimens. HIV health literacy was not assessed in this study. Garcia-Teague⁹ conducted a descriptive study of adherence to treatment in low-income Latinas receiving treatment in community-based clinics ($n = 60$) and found that 57% ($n = 34$) reported more than 95% adherence to their medication regimens. Disruptions in psychosocial well-being and difficulty understanding clinic staff accounted for 27% of the variance in treatment nonadherence (a combined measure of clinic appointment keeping and medication adherence). Low-income Latinos may be at relatively greater risk than other groups for low health literacy and poor adherence due to problems of accessing care and utilizing services.

Adherence enhancement program

Reports of the effects of adherence intervention programs are limited. A recent review of published and abstracted reports on adherence intervention studies revealed only 11 studies measuring intervention effectiveness outcomes; only 4 had been published.⁵ Furthermore, only 5 of these studies were randomized trials and none reported sustained intervention effects. There is some evidence that multicomponent cognitive-behavioral and education approaches may be effective. Murphy and colleagues¹⁰ reported on the results of a small pilot trial of a multicomponent cognitive-behavioral therapy and nursing program to promote adherence. These authors found significantly higher levels of efficacy to communicating with clinic staff and to maintaining treatment. However, the intervention did not appear to significantly improve adherence to the recommended dose of their medication.

There have been a few randomized adherence trials that have shown efficacy in improving adherence. Although not targeted at

Latinos, given the rarity of such studies, they need further discussion. Levy and colleagues¹¹ evaluated the impact of a multidisciplinary HIV adherence intervention for patients attending an ambulatory clinic at a large public hospital using both generalized education conducted by the study pharmacist and/or nurse and individualized follow up. Using multiple observations, they reported a significant decrease in self-reported number of missed doses for 4-, 7-, and 28-day time periods and a decrease in Morisky score, indicating an improvement in medication-taking behavior before and after the intervention. A crucial component of the adherence intervention included the identification of patient specific barriers to adherence and the formulation of strategies to circumvent these barriers.

In the design of the treatment adherence enhancement program for low-income Spanish-speaking Latino men and women (*Es Por La Vida*), strategies to improve HIV health literacy and relationships and communications with medical providers were emphasized in an effort to improve adherence behaviors. The primary goals of the program were to improve HIV-related health literacy and patient interactions with their care providers. According to various reports, the accepted distinguishing characteristics of health-literate individuals include the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.¹² Furthermore, individuals' health literacy skills and capacities are influenced by their education, culture, and language.¹³ It follows that HIV-related health literacy would include those skills and knowledge to obtain, process, and understand HIV-related information, and that these skills and knowledge are influenced by the particular educational level, culture, and language of the group in question.

Informational support was deemed critical.

The specific aims of the instructional modular program, conducted in Spanish by bilingual treatment advocates and a nurse practitioner, were to improve HIV health literacy and to teach respectfully assertive communications to improve disclosing and receiving key information in conversations with their physicians and nurses. The instructional modular content pre-

sented in small groups included a broad range of didactic information as well as interactive group experiences designed to enhance participants' HIV knowledge and treatment in a manner that was consistent with the education, culture, and language of the participants and to make learning pleasurable and create behavior change. Content areas included: (1) basic HIV/AIDS information, (2) barriers and facilitators of adherence management, (3) maintaining quality of life and controlling illness-related stress, (4) reducing risks related to transmitting HIV and management of substance use, and (5) communication skills with their physicians and other health care providers and maintaining effective family and community support systems. The program consisted of the 5-week instructional support modular program with a 6-month follow-up nurse case-management component focusing on the barriers to adherence and strategies to minimize these barriers.

Particular attention was given the need to introduce information in ways understandable to these patients. Written materials were prepared at sixth-grade level using simple language. Attention was drawn to key points outlined and bolded. All materials were read and discussed in detail in the context of a shame-free environment to encourage discussions of any details that were confusing or unfamiliar. Additionally, concern for the acceptability of the program led to the development of culturally specific strategies for this population. For example, the core cultural value of *simpatia* (the desire to maintain harmony, politeness, and respect in relationships) was considered in program content dealing with how participants might communicate with their health providers in discussions during their clinic visits. This analysis is a follow-up of an ongoing study of the effectiveness of an adherence enhancement program for HIV-positive Latinos by these authors. The prior interim description and analyses are presented in previous publications.^{14,15}

MATERIALS AND METHODS

Participants

Participants receiving care at two administratively linked clinics in east Los Angeles were

randomly assigned to receive the intervention program (*Es Por La Vida*) and the comparison group receiving standard clinic care only. According to the clinics' Ryan White Care Act report data, the clinics serve approximately 1000 HIV-infected clients annually and admit 10–12 new patients every month. Over three quarters of the clinics' patients are Latino and male. Additionally, almost all patients report incomes substantially below the Federal poverty level.

All clinic medical records were screened by the clinical trials staff; 176 patients were identified by these staff as eligible for the study using the following criteria: male or female, 18 years or older, and had problems with medication adherence as charted in the patients medical record (progress notes). Clinical trial staff contacted all eligible patients by phone and or letter; however, 19 could not be reached by phone or could not receive mail (16 disconnected phones and 3 individuals were homeless) and 6 patients did not qualify because either they had changed their primary place of care or were not a clinic patient according to medical records.

The remaining 151 potential participants were screened a second time by clinic staff to ensure that they met all study criteria: Spanish-speaking, detectable viral load, stated problem with adherence, and taking antiretroviral medications for at least 3 months. Patients had both a problem with adherence as well as a detectable viral load; those having adherence problems with undetectable viral loads were excluded from the study. An additional 58 patients did not meet study criteria for the following reasons: 3 patients did not speak Spanish, 1 could not be located (was out of town), 12 were not taking antiretroviral medications, 26 had undetectable viral loads according to most recent laboratory data, 6 declined to participate giving no reasons, 1 was not feeling well, 4 were too busy, 1 stated that participation would be too inconvenient (she did not want to be out late), and 4 were no shows.

The final sample of 93 potential participants were consented, enrolled, and randomized (20 at a time) to either the pilot intervention or comparison group. Of these, 8 additional participants were excluded for the following reasons: 3 did not show and were unable to be

contacted, 1 never started medications despite claiming he was taking medications, 3 had undetectable viral loads, and 1 was reassigned to a clinic specializing in HIV and pregnancy. The remaining sample of 85 included 42 intervention- and 43 comparison-group participants. Once qualifying and starting the program, all patients remained in the study. Being naive to medication, on or off medication, and numbers of previous medication combinations, were not considered in including participants. Changes in medication, discontinuation of a medication or the addition of another, did not constitute a reason to drop participants from the study. None of these patients were taken off anti-retroviral therapy.

While 42 pilot program and 43 comparison group participants were initially enrolled, 2 participants in each group (a total of 4) were lost to follow-up and were unable to be reached initially after the instructional component of the program. Baseline and 6 weeks (immediately after instructional modular program) data were available for 41 intervention and 40 comparison group patients. From 6 weeks to 6 months, an additional 5 participants in the comparison group and 7 participants in the pilot group were lost to follow-up, for an attrition rate of 21% for the intervention group and 17% for the comparison group. Analysis of the characteristics of these 16 patients revealed that they had a poorer understanding of HIV terms (11.00 versus 13.38) [$F(1,82) = 3.96, p = 0.05$] and a statistically significant higher viral load than those who remained (99,328 versus 36,973) [$F(1,83) = 4.34, p = 0.04$]. They were also less apt to take part in decisions about their care (1.88 versus 2.41) [$F(1,82) = 4.62, p = 0.03$].

Procedures

The University's Human Subject's Protection Committee and the Internal Review Committee at the participating clinic granted approval for conducting the study. Signed informed consent was obtained from all participants in the study.

Data used in these analyses were gathered from chart review and direct face-to-face interview. Potential participants enrolled in the study were first screened by the clinic's clinical

trial staff on the basis of time since diagnosis (3 months), receiving HAART for at least 3 months, and whether problems with medication adherence were noted in the patient progress notes in the medical record. Upon enrollment, all participants received a code number from a published table of random numbers and assigned to either the pilot intervention group or comparison group.

Modular instruction was provided by the nurse practitioner and health educators to pilot group patients only and included five sequential sessions aimed at increasing patients' HIV knowledge and abilities to communicate with medical staff. After these modular sessions, phone call and face-to-face encounters with the nurse practitioner were conducted with pilot group participants. In contrast to the modular instruction, the focus of the nurse case-management sessions was to address patients' unique actual or potential risks for non-adherence using problem-solving and motivational interviewing strategies starting with where the patient was. These sessions included reviewing content that they not having fully understood in the group sessions, identifying ways to lower barriers to change, problem solving ways to address specific barriers to adherence management, and identifying community, treatment, and social support services or referrals to help them to address barriers to adherence. This follow-up strategy was important in verifying the patient's understanding by having them summarize what they were to do and what the nurse practitioner would do.

Data on HIV health literacy, patient-provider relationships, and medication adherence were collected in interviews with participants at baseline, at 6 weeks (immediately after the instructional modular component of the program) and at 6 months (at the conclusion of the nurse case management follow up). A foreign medical graduate fluent in Spanish was trained to administer the face-to-face surveys conducted in interview format. In addition to having advanced training in HIV risk reduction and interview approaches through the Centers for Disease Control (CDC), specific training in conducting the survey included procedures for protection of human subjects and practice and feedback about potential scenar-

ios that may be encountered. This project director also collected data from the medical records including laboratory values for CD4 count and viral load and viral log changes at baseline, 3 months, and 6 months. Project meetings were held weekly to examine quality of data from the medical records and to provide assurance that interview data was collected consistently.

Measures

As indicated, assessment measures included patient self-report and medical record data including laboratory findings on all intervention and comparison group patients.

Sociodemographic characteristics. Data including age, gender, country of birth, income, primary language, and total years of education as reported by participants on the demographic portion of the survey. The process by which a person incorporates a new culture,¹⁶ was measured with Marin's 5-item acculturation subscale assessing only facility with language. Strong support exists for the validity and reliability of this scale in Latino populations.¹⁷ Scores on this scale were 1 to 5, with higher scores indicating more use of English and therefore, higher levels of acculturation.¹⁸ In this study, the Cronbach α coefficient at baseline was 0.68 for the intervention group and 0.86 for the comparison group.

Laboratory findings: health status/disease progression. Health status and disease progression were assessed with self-report and clinical laboratory information in the patients' medical charts using a modified version of the data abstraction tool to measure morbidity outcomes developed for Ryan White funded service providers. Disease progression was assessed with data about disease parameters (CD⁺ T-cell count, HIV-RNA viral load (copies per milliliter, reverse transcriptase-polymerase chain reaction [RT-PCR] assay]) as indicated in the laboratory reports. Analysis of viral load was conducted using viral load as both a continuous and categorical variable. Current viral load was recorded as the most recent viral load results, within 2 weeks of the medical chart re-

view (baseline, 3 months, and 6 months). Self-reported health status was measured with an item assessing perceived level of general health status in the past week.

Measures of health literacy. In this study, both measures of HIV health literacy and specific measures of HIV treatment literacy were used.

Modified REALM. The Rapid Estimate of Adult Literacy in Medicine or REALM in its original form is a short screening instrument designed to be used in public health and primary care settings to assess patients with low reading levels.¹⁹ REALM is preferred over other literacy measures because it assesses medical knowledge and is easily implemented with clinic populations. To make the instrument applicable for HIV patient populations, HIV terms were added to the original set of medical terms. In keeping with the format of the original REALM, 24 additional medical terms were chosen as they reflected varying levels of difficulty. For example, terms ranged from HIV, virus, and symptoms (lower level of difficulty) to terms such as viral replication, protease inhibitors, HIV-resistant strains (higher level difficulty). Individuals were asked first if they had heard these terms (recognition) and second, whether they could explain them (understanding). Two scale scores were derived: global recognition and global understanding of medical terms. Chronbach α on the combined sample for the recognition scale were 0.81 at baseline, 0.82 at 6 weeks, and 0.74 at 6 months; and for the understanding scale, 0.79 at baseline, 0.84 at 6 weeks, and 0.79 at 6 months.

HIV illness and treatment knowledge and misconceptions scale. We assessed HIV/AIDS disease and treatment knowledge and misconceptions using a 17-item survey that included basic knowledge of HIV transmission and treatment, and included common and important misconceptions. Items were derived from previous research assessing HIV-related knowledge among Latino populations about HIV transmission and prognosis^{18,20} and included items from HIV medication information pamphlets to assess potential misconceptions

about HIV antiretroviral therapy. Respondents were asked to respond to this list of 17 statements about HIV illness and treatment (10 items for HIV illness and 7 items for HIV treatment knowledge) by stating whether they thought each statement was a *Myth* or *Fact*. Examples of statements were, "You can catch HIV from a toilet seat" and "If you feel good, you don't really need to take antiretroviral medications." "Don't know" responses were coded as incorrect. To construct scale scores, correct answers were summed to form a score ranging from 0 (no knowledge) to 17 (high level of knowledge). Scores on the HIV knowledge and misconceptions about treatment subscale were positively correlated with respondents' understanding of HIV terminology ($r = 0.39, p \leq 0.001$) and better relationship and communications with their physician ($r = 0.30, p \leq 0.01$). Finally, a question about whether they believed they needed to continue taking HIV medication or experience a risk of getting sicker was used to assess the level of their understanding about the importance of medication adherence with 1 = very high risk of getting sicker, 4 = non-existent risk of getting sicker.

Relationship and communications with health care providers. Perceptions of the quality of relationship and communications with health care providers was measured with two subscales: one assessed their relationship with medical staff and the other, their relationship with their specific HIV-treating physician. The relationship/communication with medical staff (doctors and nurses) scale (7 items) included how well their medical staff explained their medication, how well they listened, and how well they answered their questions on a scale of 1 = very poor/poor to 5 = excellent/the best. Alpha reliabilities on the combined sample for this scale were 0.90 at baseline, 0.92 at 6 weeks, and 0.92 at 6 months. The second scale (9 items) refers specifically to the participants' relationship and communications with their HIV physician (the physician they saw most often in the clinic). This scale consisted of 9 questions and included how well their physician understood them and involved them in making decisions about their care. α Reliabilities on the combined sample for this scale were

0.93 (at baseline), 0.94 (at 6 weeks), and 0.93 (at 6 months).

Measures of adherence self-efficacy beliefs and self-reported medication adherence. Medication adherence self-efficacy was measured with an item from the Adult AIDS Clinical Trials Group (ACTG) Adherence Baseline Questionnaire²¹ that asked about participants level of certainty that they had mastered their medication regimen requirements. They were asked to identify how certain they were that they could take all or most of their medications correctly, 0 = not at all sure and 3 = extremely sure.

Assessment of adherence behaviors were also measured with questions from the ACTG baseline questionnaire modified for use in this study. Participants were first asked to list each of their antiretroviral medications by name with the help of a picture depicting the color, shape, and size of antiretroviral medications. They were then asked about their adherence to each of their medications for the following points in time: yesterday, the day before yesterday (2 days ago), 3 days ago, and 4 days ago. Although self-report of medication adherence is an indirect method of actual medication taking, it has predicted important virologic and immunologic outcomes.

For the purpose of this study, medication adherence to dose was analyzed in not one but a multitude of ways as recommended. First, it was calculated as a percentage of those missing 2 or more doses in the last 24 hours and last 4 days (% missing 2+ doses last 4 days and past 24 hours). Second, the proportion of doses missed per day was calculated by dividing the number of doses they should have taken by the number they took for each of the 4 days. The average proportion for the 4 days was calculated by averaging the mean proportion of doses missed for all 4 days (average 4-day proportion missed). Next, the standard of more than 90% and more than 95% adherence were used. Percentages of participants who missed on average greater than 10% or 5% of their medications during the last 4 days were calculated for both groups. Dichotomous variables were created identifying those who had greater than 90% and greater than 95% adherence to their antiretroviral medication regimen in the past 4 days.

Data analysis

Initially, baseline descriptions of the intervention and comparison group participants were analyzed using univariate statistics (means, standard deviations, and percentages). To examine the relative effectiveness of the program, comparisons were made between the intervention and comparison group on the amount of change that occurred from baseline to 6 weeks and from baseline to 6 months. Data from the two research conditions (intervention and comparison groups) were examined for equivalency using McNemar tests for comparing dichotomous measures over time. Two-sample *t* tests were used to ascertain differences in change scores between the comparison and treatment groups for each time period. Pooled *t* tests were used to examine change scores for variables with equal variances and Satterthwaite *t* tests were used for variables with unequal variances. Bivariate analyses were conducted to examine the change from baseline to both follow-ups (6 weeks and 6 months). Because there were significant differences between groups at baseline, it was important to measure the within-group change between time periods. As such these analyses do not examine the differences in scores between groups; rather, the amount of difference between time periods within each group. This procedure is important when differences between groups exist at baseline and it is not possible to simply compare groups on degree of change using which group had the larger score. To examine changes in viral load, categorical variables were constructed using the dichotomous measure of viral load \pm 400 copies per milliliter. Proportion of participants more than 400 copies per milliliter in each group were analyzed. Additionally, viral load changes were examined as a function of viral log decreases of a decrease of 0.50 or more and more than 1.00 or more logs.

With the current sample sizes there was enough power to find significance for larger effect sizes. Between baseline and 6 weeks there were approximately 40 cases per group (80 total), with a large effect size (0.7), α at 0.05, the data will have a power of 0.87 and will find significance for $t = 1.990$. At 6 months, there were

approximately 70 cases (35 per group) with a power of 0.82 and significance for $t = 1.996$ ($\alpha = 0.05$).

RESULTS

The sample of 85 participants was largely male, born outside the United States, and had less than 12 years of education. Half reported incomes less than \$500 per month and Spanish was the language spoken at home for nearly all.

Differences in intervention and comparison groups at baseline

There were no significant differences between groups with respect to age, gender, proportion born outside the United States, education, income, or language spoken at home (Table 1). The average age of the intervention group was older ($M = 42 \pm 8.3$ versus $M = 40 \pm 9.3$) and more reported average monthly incomes less than \$500 (48% versus 34%) but these differences were not significant. There were no significant differences in level of acculturation, defined as facility with language (not tabled). Both groups had less than moderate scores, less than 2 on this scale (potential range, 1–5 with 5 representing greater facility with language). More than two thirds of the entire sample reported male to male encounters as being the only possible source of their HIV infection. There were no significant differences between groups with respect to risk factors: 71.4% ($n = 30$) of the comparison group participants and 67.4% ($n = 29$) of the pilot intervention group participants reported male to male sexual encounters while 19.1% ($n = 8$) of the comparison group and 20.9% ($n = 9$) of the intervention group reported heterosexual encounters as being the only possible source of their HIV infection. One participant in each group reported injection drug use (IDU); and this was IDU only and IDU with male-to-male sexual encounters.

Those in the comparison group were diagnosed more recently 4.8 years versus 7.6 years [$F(1,83) = 8.02, p = 0.01$] and to have spent less time on antiretroviral therapy (ART), 44.7 months versus 61.4 months [$F(1,81) = 4.20, p =$

TABLE 1. DEMOGRAPHIC CHARACTERISTICS, HEALTH/TREATMENT, AND ADHERENCE INDICATORS AT BASELINE

Factors and indicators	Range		M/%		SD	
	Comparison group (n = 42)	Pilot group (n = 43)	Comparison group (n = 42)	Pilot group (n = 43)	Comparison group (n = 42)	Pilot group (n = 43)
Demographic characteristics:						
Age	21–78	31–65	39.5	41.8	9.3	8.3
Gender (% male)			92.9%	88.4%		
Born outside US (%)			92.9%	97.5%		
Education (% <12 years)			85.4%	76.7%		
Income (% ≤\$500/month)			34.2%	47.6%		
Language at home (Spanish)			71.4%	79.1%		
Male-to-male sex risk factor			50.8%	49.2%		
Health status and treatment:						
CD4 cells per mm ³	24–1346	4–1084	377	212	341	199**
CD4 < 200 cells per mm ³			46.34%	55.81%		
Viral load (copies per milliliter RT-PCR)	25–471,935	25–708,576	31,387	65,632	88,457	126,308
Viral load >400 copies per milliliter			45.2%	67.4%*		
Time since diagnosis (years)	0–17	0–18	4.8	7.6	3.91	4.92**
Time on ART (months)	0–120	0–144	44.7	61.4	33.94	39.82*
Adherence measures:						
Proportion nonadherence (last 4 days)	0–0.88	0–0.60	0.05	0.06	0.15	0.12
Ave. percentage > 95%			72.50%	68.29%		
Ave. percentage > 90%			85%	80.49%		

* $p < 0.05$; ** $p < 0.01$.

US, United States; RT-PCR, reverse transcriptase-polymerase chain reaction; ART, antiretroviral therapy.

0.04]. There were no statistically significant differences between groups on absolute viral load; however, the groups did differ using the criteria, more than 400 copies per milliliter. Forty-five percent of the participants in the comparison group had viral loads less than 400 copies per milliliter versus 67% of those in the pilot group [$\chi^2(1) = 4.26$, $p = 0.04$]. Using CD4 count, there were statistically significant differences between groups on absolute CD4 count (mean for the comparison group was 377 and the pilot group, 212) [$F(1,85) = 7.42$, $p = 0.01$], but no differences between groups having CD4 counts less than 200 cells per mm³. Forty-six percent of the comparison group members had CD4 counts less than 200 compared to 56% in the pilot group. Further, no statistically significant differences were found with any of the antiretroviral adherence measures at baseline.

HIV health literacy

Table 2 indicates that HIV knowledge (global HIV disease knowledge) significantly in-

creased more for the intervention group than for the comparison group from baseline to the 6-week follow-up ($t = 2.22$, $p = 0.03$). Significant differences were also shown on measures of recognition and understanding of HIV terms. Recognition of HIV terms showed the greatest difference between intervention and comparison groups for both time periods (baseline to 6 weeks ($t = -2.97$, $p < 0.0001$); baseline to 6 months, ($t = -3.16$, $p < 0.0001$).

These same results occurred for understanding of HIV terms: baseline to 6 weeks ($t = -3.52$, $p < 0.0001$) and baseline to 6 months ($t = -3.93$, $p < 0.0001$) (Scatterthwaite t test for unequal variances). Recognition of HIV terms increased by about 4–5 points for the intervention group for both time periods and only 1 point for the comparison group for these same time periods. The comparison group did not show much difference in changes in understanding HIV terms, but the intervention group increased by 5 points from baseline to 6 weeks follow-up and by 6 points from baseline to 6 months follow-up (Table 2). There was a trend in the difference in perceived risk of discontin-

TABLE 2. CHANGES IN OUTCOME VARIABLES, BASELINE TO SIX WEEKS AND BASELINE TO SIX MONTHS

Outcome variables	Comparison group				Pilot group			
	Baseline—6 wk (n = 40)		Baseline—6 mo (n = 35)		Baseline—6 wk (n = 41)		Baseline—6 mo (n = 34)	
	M	SD	M	SD	M	SD	M	SD
Health literacy measures:								
Global HIV disease/treatment knowledge	1.03	2.31	1.40	2.59	2.28	2.67*	1.20	3.19
HIV treatment-related knowledge subscale	0.95	1.70	0.89	2.07	0.72	1.90	1.09	2.02
Recognition HIV terms	1.13	4.24	1.34	3.76	4.23	5.02****	4.66	4.80****
Understanding HIV terms	1.30	4.94	1.91	3.60	5.49	5.63****	6.16	7.97****
Knowledge risk getting sicker	-0.03	0.67	0.09	0.67	-0.07	0.85	-0.24	0.78*
Adherence measures:								
2+ doses missed last 4 days	14.61%		6.79%		-15.34%		-5.69%	
2+ doses missed past 24 hrs	5.66%		18.21%		-4.1%		-0.34%	
Ave proportion missed doses last 4 days	0.01	0.19	0.04	0.13	-0.01	0.13	0.02	0.14
Proportion > 95% adherence last 4 days	-11.97%		-4.85%		8.03%		1.71%	
Proportion > 90% adherence last 4 days	-11.32%		-11.47%		11.62%		-0.49%	
Self-efficacy adherence management	-0.08	0.92	-0.06	0.59	0.27	0.92*	0.12	0.95
Follow med special instructions 4 days			0.06	0.34			-0.07	0.36
Follow med schedule 4 days			-0.09	1.60			0.33	1.58
Relationship/communications:								
With HIV-treating physician	0.58	6.70	-1.17	6.85	3.59	6.32**	7.09	8.04****
With medical staff (doctors and nurses)	0.78	5.71	1.11	5.97	2.08	5.66	5.28	5.37****
Health status indicators ^a :								
Viral load (> 400 copies per milliliter RT-PCR)	-11.01%		-6.19%		3.76%		3.76%	
Drop VL log ≥ 1.00	6.25%		11.43%		14.24%		37.14%***	
Drop VL log ≥ 0.50	9.38%		14.29%		17.14%		37.14%	
CD4 > 200	18.59%		14.29%		-6.64%		-7.83%	
Self-reported general health status	-0.03	1.03	0.09	0.95	0.17	1.09	0.47	1.21

^aViral load and CD4, baseline to 3-months and baseline to 6-months for each group.

* $p \geq 0.10$; ** $p < 0.05$; *** $p < 0.01$; **** $p < 0.001$.

SD, standard deviation; VL, viral load; RT-PCR, reverse transcriptase-polymerase chain reaction.

uing medications favoring the pilot group, a change in perception about the need to stay on ARV medication or risk getting sicker (1 = very high risk of getting sicker, 4 = nonexistent risk of getting sicker). A decrease indicates an increase in their perception of being at risk. At follow up, there was a trend for the intervention group to perceive themselves as being at greater risk of becoming sicker if they discontinued antiretroviral medications ($t = 1.84, p = 0.07$).

Communications and relationships with medical staff and HIV physicians

Over the course of the study, pilot group participants showed a significant improvement in their relationships and communications with their HIV-treating physicians and medical staff (Table 2). Pilot group participants' relationship and communications with their HIV-treating physicians improved from baseline to 6 weeks ($t = -2.06, p = 0.04$) and from baseline to 6 months ($t = -4.54, p < 0.0001$). The pilot group also showed improvement in communications with medical staff from baseline to 6 months ($t = -2.99, p = 0.004$). In contrast, the comparison group showed little change in either measure for any time point.

Self-reports of adherence

There was a trend for pilot group participants to more likely report that they were able to take their medications as directed, compared to comparison group participants, during the baseline to 6 weeks time period ($t = -1.68, p = 0.10$). The intervention group showed a one-quarter point increase in medication adherence self-efficacy, and the comparison group showed a six-hundredth of a point decrease during this time period. Examining adherence behaviors as dichotomous measures, the comparison group showed a significant increase in nonadherence compared to the pilot group. The pilot group reported missing doses in the past 4 days and the past 24 hours with the largest decrease in 2 or more dosages missed being within the first 6 weeks. However, the change at 6 months was not as striking. In contrast, the comparison group reported a greater likelihood of missing 2 or more doses within both 4 day and 24-hour

time frames. However, the only change nearing significance was found in the comparison group in the baseline to 6 month follow up with missing 2 or more doses in the past 24 hours (McNemar = 3.60, $p = 0.06$) (Table 2).

There were no statistically significant differences between the pilot and comparison groups on missed doses in the past 4 days. Using the criteria, greater than 90% adherence, there were no significant difference in degree of change between groups. However, the comparison group showed a decline in proportion reporting greater than 90% adherence at 6 weeks and 6 months, while the pilot group showed an increase in proportion reporting greater than 90% adherence at 6 weeks but the increase was not sustained at 6 months. Using the criteria of greater than 95% adherence (those missing one or more doses in 4 days), the pilot group showed a greater (but not significant) increase in proportion of persons being adherent than the comparison group; baseline to 6 weeks, -11.97% for the comparison group and 8.03% for the pilot group. From baseline to 6 months, -4.85% of comparison group members and 1.71% of pilot group participants were more than 95% adherent. The pilot group showed some improvement in other adherence measures, but none were statistically significant.

Health status

As previously noted, while there were no statistically significant differences in the intervention and comparison groups with respect to viral loads greater than 400 copies per milliliter, they did differ on absolute viral load with the comparison group having a lower viral load. Examining the changes in viral load from baseline to 6 weeks and baseline to 6 months revealed differences between the groups but these were not significant. The comparison group had fewer people with viral loads more than 400 copies per milliliter (an 11% decrease from baseline to 6 weeks and a 6% decrease from baseline to 6 months). The pilot group had an increase of 4% in those with viral loads more than 400 copies per milliliter from baseline to 6 weeks with no change occurring between 6 weeks and 6 months. However, these findings

were not statistically significant. A significant difference was found between comparison and pilot groups in whether individuals had a drop in viral log greater or equal to one, [$\chi^2(1) = 6.29, p = 0.01$] and greater or equal to 0.50 [$\chi^2(1) = 4.79, p = 0.03$]. In other words, the pilot group showed a greater drop in log measurement from baseline to 6 months follow up using both a log difference of 0.50 and 1.00.

The association between greater than 95% adherence at both 6-week and 6-month follow-ups (consistent adherence) and whether there was a significant change in viral load from baseline to 6 month time periods was examined. Those with consistent adherence had a greater decrease in viral load from baseline to 6 months (consistent adherence = -49,512 decrease in viral load from baseline to 6 months and inconsistent adherence = 6304 increase in viral load from baseline to 6 months). However, this was not statistically significant. Further examination found the difference between consistent and inconsistent/non-adherence and change in viral load for those in the pilot group to be a trend but not statistically significant, [$F(1,32) = 2.94, p = 0.10$]. Within the pilot group, those with consistent adherence had a decrease in viral load by 85,670 on average, while those with inconsistent adherence or nonadherence at 6 weeks and 6 months had an increase in viral load by 33,243 on average. The comparison group showed a decrease in viral load regardless of adherence, but these changes were not statistically significant.

DISCUSSION

As antiretroviral therapy becomes more complex, requiring very high standards of adherence, patients' understanding of their treatment becomes critical. It follows that patients require more knowledge of their condition and treatment and necessary skills in communicating with their medical providers to ensure optimal treatment efficacy. Particular concern should be raised for populations whose levels of health literacy may be low and whose access to and utilization of services, for a variety of reasons, might be limited.

This study evaluated a medication adherence enhancement program, relative to a compari-

son group, in improving HIV health literacy and patient-provider relationship and communications and subsequent adherence behaviors over a 6-month period. While reports of the effects of adherence intervention programs are limited, there is some evidence that multi-component programs are effective. For example, Murphy and colleagues¹⁰ reported the results of a small pilot trial of a multicomponent cognitive-behavioral therapy and nursing program to promote adherence and demonstrated that significantly higher levels of efficacy to communicate with clinic staff and to continue treatment, and a trend toward an increase in taking medications as scheduled were found. However, the intervention did not appear to significantly improve adherence to dose. And, only one Latina/o was enrolled in this study. Exactly what interventions and how these may be adapted for use in a variety of populations was not fully explored.

In this study differences between the pilot and comparison groups were shown on disease management skills (health literacy and patient-provider communications) in keeping with the primary focus of the intervention. There were significant differences between groups on improvement on most measures of HIV health literacy. Although patients in the intervention group, on average, had lower levels of HIV-related knowledge and recognized fewer HIV-related terms at baseline, their improvements at 6 weeks and 6 months on measures of health literacy (recognition and understanding of HIV terms) were significantly better than those in the comparison group. Consistent with these findings was a trend for the patients in the intervention group to report greater adherence self-efficacy, baseline to 6 weeks. Changes in patient-provider relationships were also more apparent in the pilot group at both follow-up periods (6 weeks and 6 months) with little change in the comparison group.

The impact on adherence behaviors was less obvious. Changes favoring improved dosage adherence at more than 95% or more than 90% in the intervention group were not statistically significant. While these differences were not significant, there were trends approaching significance with other measures of adherence.

For example, the comparison group reported a greater increase in missing 2 or more doses in the last 24 hours, baseline to 6 months, compared to those in the intervention group.

Initial differences between groups on viral load (more than 400 copies per milliliter) and absolute CD4 count were consistent with findings that comparison group members received a diagnosis sooner and entered the study in better health. There were, however, no statistically significant differences between groups on absolute viral load and CD4 counts more than 200 cells per mm³ at baseline. The pilot group showed a very slight increase in those with more than 400 copies, but no further increases in viral load more than 400 copies per milliliter were detected at 6 months. Viral load changes were most evident in the pilot group with a greater drop in log measurement from baseline to 6 months follow up using both a log difference of 0.50 and 1.00.

The results of this study must be interpreted with caution. Further study of the effects of the program is warranted. Future research might identify what part of the intervention is critical to promoting HIV health literacy and adherence and what part is useful but not essential. The lack of significant findings in self-reported medication adherence may be because of a number of design constraints. Although larger than that of some studies, the sample size was sufficient to detect large effects but insufficient to determine significant treatment effects. This places significant limitations on the ability to detect differences in the comparison and intervention groups over time. More subtle changes could not be detected.

This study added to the literature by reporting changes in virologic outcomes. While other studies have noted improvement in virologic outcomes, many have only offered descriptive information without testing for significance.²² Assessing significant changes in virologic outcomes and interpreting their meaning is not straightforward. A detectable viral load is only one measure of adherence. Of particular concern is the timing of collection of survey data to correspond with biological markers. In this case viral load readings and adherence data from surveys at baseline and again at 6 months were most useful. Although there is an associ-

ation between adherence and viral load, the association is not perfect.²³ Some patients with adherence problems could continue to have undetectable viral loads for some time after exhibiting adherence problems. Nonadherent patients with undetectable viral loads were excluded from this study and this presents a potential limitation of this study. Furthermore, a high viral load does not necessarily mean the individual is nonadherent. Many of these patients in this study were antiretroviral experienced and had developed viral resistance prior to the study. As such, even 100% adherence in a pan-resistant patient will not result in adequate viral control. Also, there were new medications being introduced at variable times to rescue the resistant-virus patient that confounds which factor resulted in viral control: better adherence or better medicine. We did not examine if medication changes affected clinical outcomes. Perhaps working exclusively with antiretroviral naive patients would have shown more significant viral control differences between groups.

Second, self-report was the only measure of adherence behaviors. While self-report has been found to be significantly associated with changes in viral load,²⁴ additional measures of medication adherence using multimodal approaches, namely, medication electronic monitoring systems (MEMS), pill count, pharmacy refill records, and self-report, would strengthen outcome measurement. Deriving composite adherence scores when multiple methods of measuring medication adherence are may be more effective in predicting viral load changes and understanding of the effects of any adherence enhancement program on adherence management. Advances in constructing composite adherence scores (CAS) have been described^{25,26} and offer increased validity in determining the effects of adherence enhancement programs on medication adherence behaviors.

CONCLUSIONS

A unique facet of this study is that it was conducted with low-income, low-literate Spanish-speaking Latino men and women, most of

whom were not born in the United States, inherent in the design of this treatment adherence enhancement program providing culturally and linguistically appropriate content and skills training. Because of the low literacy levels of the population targeted in this pilot, level of HIV related health literacy and patient-provider communications were believed to be critical targets in an adherence enhancement initiative. It is important to consider that literacy problems require more time to strengthen patients' self-care skills and knowledge. Together with the fact that high levels of adherence are difficult to achieve in even the most knowledgeable patient, abbreviated short-term interventions are not likely to be efficacious with these groups. Additionally, sensitivity to the feelings of patients with low literacy about their lack of knowledge is important and requires that information be offered in ways not to embarrass them. Under these circumstances, particular care is needed in both assessing knowledge deficits and promoting patient learning about their disease and treatment.

Intervention strategies useful to other groups with moderate to high levels of HIV knowledge may have insufficient impact on those who have limited baseline knowledge of their condition and treatment. In this program, cognitive-behavioral educational strategies were used to increase patients' knowledge and self-efficacy in managing adherence and communicating effectively with medical providers; however, cognitive-behavioral therapy was not provided, nor was any other systematic stress management training. Simoni and colleagues¹⁹ concluded that a variety of approaches have been used to enhance adherence with varying levels of effectiveness. Furthermore, while pharmacist-led individualized intervention, a cue-dose training combined with monetary reinforcement, and self-efficacy promoting cognitive and behavioral educational intervention programs have shown some promise, to date most programs have been small pilot studies and exhibit methodological problems which limit confidence in encouraging findings. Any further testing of this program requires attention to the limitations noted.

In conclusion, multiple factors influence medication adherence and many of these factors may not be amenable to change with short-term enhancement programs. This program targeted two major factors influencing adherence that were modifiable: health literacy and patient-provider relationship and communications. It is conceivable that patients can not be sufficiently motivated toward adherence unless they first understand their disease and treatment. HIV-related health literacy and patient-provider communications were deemed to be primary critical targets in this adherence enhancement initiative. While the results were promising, further research is needed to examine the impact of this adherence enhancement program on this population of low-income, low-literate HIV-positive men and women receiving care in community-based settings.

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REFERENCES

1. Centers for Disease Control and Prevention. HIV/AIDS among Hispanics in the United States 2002. www.cdc.gov/HIV/pubs/facts/Hispanic.html (Last accessed August 30, 2005).
2. HIV Epidemiology Program, Los Angeles County Department of Health Services. Epidemiological Profile of HIV/AIDS in Los Angeles County 2000. Los Angeles, California, 2002.
3. Bozzette SA, Berry SH, Duan N, et al. The care of HIV-infected adults in the United States: Results from the HIV cost and services utilization study. *N Engl J Med* 1998;339:1897-1904.
4. Ickovics JR, Meisler AW. Adherence in AIDS clinical trials: A framework for clinical research and clinical care. *J Clin Epid* 1997;50:385-391.

5. Fogarty L, Roter D, Larson S, Burke J, Gillespie J, Levy R. Patient adherence to HIV medication regimens: A review of published and abstract reports. *Patient Educ Couns* 2002;46:93–108.
6. Kalichman SC, Ramachandran B, Catz S. Adherence to combination antiretroviral therapies in HIV patients of low health literacy. *J Gen Intern Med* 1999;14:267–273.
7. Kalichman SC, Rompa D. Functional health literacy is associated with health status and health-related knowledge in people living with HIV-AIDS. *J Acquir Immune Defic Syndr* 2000;25:337–344.
8. Murphy DA, Roberts KJ, Hoffman D, Molina A, Lu MC. Barriers and successful strategies to antiretroviral adherence among HIV-infected monolingual Spanish-speaking patients. *AIDS Care* 2003;15:217–230.
9. Garcia-Teague L. Factors associated with appointment and medication adherence in low-income Latinos living with the human immunodeficiency virus [doctoral dissertation]. University of California, Los Angeles, 2000.
10. Murphy DA, Lu MC, Martin D, Hoffman D, Marelich WD. Results of a pilot intervention trial to improve antiretroviral adherence among HIV-positive patients. *J Assoc Nurses AIDS Care* 2002;13:57–69.
11. Levy RW, Rayner CR, Fairley CK, et al. Multidisciplinary HIV adherence intervention: A randomized study. *AIDS Patient Care and STDs* 2004;18:728–735.
12. Nielsen-Bohlman L, Panzer AM, Kindig DA, for the Board on Neuroscience and Behavioral Health, Institute of Medicine. *Health Literacy: A Prescription to End Confusion*. Washington, D.C.: The National Academies Press, 2004.
13. Adams K, Corrigan JM, eds., for the Board on Health Care Services, Institute of Medicine. *Priority Areas for National Action: Transforming Health Care Quality*. Washington, D.C.: National Academies Press, 2003.
14. van Servellen G, Carpio F, Lopez M et al. Program to enhance health literacy and treatment adherence in low-income HIV-infected Latino men and women. *AIDS Patient Care STDs* 2003;17:581–594.
15. van Servellen G, Brown JS, Lombardi E, Herrera G. Health literacy in low-income Latino men and women receiving antiretroviral therapy in community-based treatment centers. *AIDS Patient Care STDs* 2003;17:283–298.
16. Marin G, Sabogal R, Marin B, Ostero-Sabogal R, Perez-Stable E. Development of a short acculturation scale for Hispanics. *Hisp J Behav Sci* 1987;9:183–205.
17. Marin G, Marin B. *Research with Hispanic Populations*. Newbury Park, Ca.: Sage Publications, 1991.
18. Gomez CA, Marin BV. Gender, culture, and power barriers to HIV prevention strategies for women. *J Sex Res* 1996;33:355–362.
19. Davis TC, Long SW, Jackson RH, et al. Rapid estimate of adult literacy in medicine: A shortened screening instrument. *Fam Med* 1993;23:391–395.
20. Flaskerud JH, Uman G. Directions for AIDS education for Hispanic women based on analyses of survey findings. *Public Health Rep* 1993;108:298–304.
21. Chesney MA, Ickovics JR, Chambers DB, et al. Self-reported adherence to antiretroviral medications among participants in HIV clinical trials: The AACTG adherence instruments. Patient Care Committee & Adherence Working Group of the Outcomes Committee of the Adult AIDS Clinical Trials Group (AACTG). *AIDS Care* 2000;12:255–266.
22. Simoni JM, Frick PA, Pantalone DW, Turner BJ. Antiretroviral adherence interventions: A review of current literature and ongoing studies. *Top HIV Med* 2003;11:185–198.
23. Weiner L, Riekert K, Ryder C, Wood LV. Assessing medication adherence in adolescents with HIV when electronic monitoring is not feasible. *AIDS Patient Care STDs* 2004;18:527–538.
24. Haubrich R, Little S, Currier J, et al. The value of patient-reported adherence to antiretroviral therapy in predicting virologic and immunologic response during unrestricted therapy. *AIDS* 1999;13:1099–1107.
25. Liu HH, Golin C, Miller LG, et al. A comparison study of multiple measures of adherence to HIV protease inhibitors. *Ann Intern Med* 2001;134:968–977.
26. Golin CE, Liu H, Hays RD, et al. A prospective study of the predictors of adherence in combination antiretroviral medication. *Gen Intern Med* 2002;17:756–765.

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