Results of a Pilot Intervention Trial to Improve Antiretroviral Adherence Among HIV-Positive Patients

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*A small pilot trial of a multicomponent (behavioral strategies, simplified patient information, and social support) and multidisciplinary (cognitive-behavioral therapy and nursing) medication adherence intervention was conducted for HIV-infected adults prescribed antiretrovirals. Patients (*N = *33) were randomly assigned to the intervention condition or standard care. Compared to the control group, patients in the intervention condition had significantly higher self-efficacy to communicate with clinic staff (*p = *.04) and to continue treatment (*p = *.04), were significantly more likely to be using behavioral and cognitive strategies (*p = *.01 and* p = *.04), reported significantly higher life satisfaction (*p = *.03), reported significantly increased feelings of social support (*p = *.04), and showed a trend toward an increase in taking their medications on schedule (*p = *.06). The intervention, however, did not appear to affect health-related anxiety or to significantly improve adherence to dose. Implications for future intervention planning are discussed.*

Key words: *intervention, medication adherence, cognitive-behavioral*

The powerful new combination antiretroviral therapies for HIV-infected patients, which couple old and new antiretroviral drugs known also as highly active antiretroviral therapy (HAART), have resulted in inhibition of viral replication and reduction of viral load to a point where viral particles are undetectable in the blood. However, such treatment regimens are effective only if patients are willing and able to adhere to complicated treatment regimens indefinitely. Interruptions in medication adherence can permit the virus to resume its typical rapid replication—as many as 10^{10} viral particles produced per day (Ho et al., 1995; Perelson, Neumann, Markowitz, Leonard, & Ho, 1996). Poor adherence to antiretroviral drugs can result in the development of resistance by HIV to multiple drugs—and to whole classes of drugs. This can result in a generation of resistant mutant strains that are no longer responsive to available antiretroviral drugs. Therefore, adherence failure carries the potential for clear clinical harm by viral rebound with the emergence of viral resistance (Friedland, 1997).

Adherence is defined as the extent to which a patient's health-related behaviors correspond with

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medical advice (Eldred, 1997). The current recommendations for antiretroviral therapy use in HIV-infected adults from the International AIDS Society–USA Panel include constant assessment of adherence, with at least 95% adherence needed for best results in therapy (Carpenter et al., 2000). This level of almost perfect adherence is extremely difficult for patients prescribed HAART. For example, a recent study conducted with HIV-infected adults found the typical medication regimen to have an average of 14.7 doses per day, with a range of up to 36 doses per day (Murphy, Roberts, Martin, Marelich, & Hoffman, 2000). Moreover, some of the medications require patients to follow specific dietary restrictions (e.g., fasting, taking with high-fat meals), and adverse side effects are not uncommon.

Studies specific to antiretroviral adherence among HIV-infected patients have found poor rates of adherence. Singh et al. (1996) reported that 63% of patients were adherent, with adherence defined as taking greater than 80% of the prescribed medication. Similarly, Balestra et al. (1996) found that 53.5% of patients were nonadherent. In another study, 70% of patients admitted that they omitted drug doses (Chow, Chin, Fong, & Bendayan, 1993). Finally, one study found that only 5.9% of patients reported full adherence, with a mean level of adherence of 56% (Murphy, Roberts, Hoffman, Molina, & Lu, in press). Among HIV-infected adolescents the rates are even lower, with only approximately 41% reporting consistent adherence (Murphy, Wilson, Durako, Muenz, & Belzer, 2001).

Although medical research is focusing on ways to simplify medication dosages (e.g., developing drugs with fewer side effects, combining two drugs in a single capsule, developing longer lasting drugs, developing drugs with no adverse interactions with food or other drugs), it is clear that HIV-infected patients will continue to be faced with a significant medication adherence challenge. Interventions to assist patient adherence are needed. Even interventions that only increase adherence levels moderately could have important clinical significance for patients. For example, one study showed that a decrease of 10% in adherence was associated with a doubling of HIV RNA level, suggesting that small differences in adherence may result in major differences in virological control (Bangsberg et al., 2000).

Over the past three decades, for many different diseases, noncompliance has been a significant problem for medical practice. The extent of the complexities surrounding adherence to antiretrovirals are beyond those encountered among most other illnesses. Nonadherence to antiretroviral therapy has been noted to be one of the greatest public health challenges associated with the management of HIV/AIDS (Kennedy, 2000). HIV-infected patients are in the extremely difficult position of needing to strive for perfect (100%) adherence, as opposed to previous adherence definitions of success for other illnesses of approximately 80%. It is well documented that the medication adherence to antiretroviral therapy is extremely difficult for patients (Murphy, Roberts, et al., 2000; Murphy et al., 2001; Samet et al., 1992). Recently, new complications have emerged, among them side effects caused by the drugs themselves and growing viral resistance (Maugh, 2002). However, the fields of behavioral medicine, health psychology, and health behavior change are well established and have given rise to social learning principles that have been used to assist in improving other health behaviors. These include smoking cessation, cardiovascular risk reduction, management of chronic pain, reducing the conditioned negative effects of chemotherapy in the treatment of cancer, and risk reduction for obesity and substance abuse (Compas, Haaga, Keefe, Leitenberg, & Williams, 1998; Kelly, 1995). In fact, support for the efficacy of social learning theory, cognitive-behavioral and behavioral interventions is relatively stronger than for other models of intervention across many of those health behaviors (Compas et al., 1998).

Specific to medication adherence, behavior change strategies have been found to be successful in improving adherence (e.g., Dunbar, Marshall, & Hovell, 1979; Haynes, 1979; Morisky et al., 1990; O'Brien, Petrie, & Raeburn, 1992). In addition, a variety of methods have been found to be successful in improving adherence (O'Brien et al., 1992). These include social support (Bloom, 1990; Martin & Dubbert, 1986; Spiegel, Bloom, & Yalom, 1981) and simplified patient education information (Ley, 1976). In the current study, all three of these components (behavior change strategies, social support, and simplified education information) were included in the intervention trial. Moreover, because it is essential to place health psychology interventions in the general context of

health care systems (Compas et al., 1998), since psychological interventions complement and work in conjunction with biomedical interventions, the proposed intervention for this study was designed as an interdisciplinary intervention. The intervention group facilitators consisted of a behavioral psychologist and a nurse practitioner. It was hypothesized that patients assigned to the intervention condition would be more likely to be adherent to antiretroviral medications than those patients in the standard care condition.

Methods

Participants

Study participants consisted of 52 HIV/AIDS patients recruited from an HIV clinic through fliers distributed to medical providers working with HIV/AIDS patients and through advertisements in publications serving the HIV/AIDS population. Eligibility criteria consisted of the following: older than 18 years; HIV-positive or AIDS diagnosis; prescribed HAART; English speaking; no participation in any medication adherence study; no current participation in a clinical trial; and no psychiatric condition that would make the patient unable to participate in a group experience, as assessed by referring physician or observed by interviewer during intake. At the clinic, potential participants were referred by their primary care provider if the provider knew the patient had experienced a problem with adherence or by the clinic nurse if her review of the medical record revealed documentation indicating problems with adherence. Participants were informed of the study by the clinic staff, and their permission was obtained to be approached by research staff, who further explained the study and conducted the informed consent process. Self-referred volunteers had approached the research staff directly. Of 170 volunteers invited to participate, 15 were self-referred. The enrollment of these volunteers was handled in the same manner as patients who were referred by clinic staff.

To confirm difficulty in adherence at enrollment into the study, the patients were asked to report how often they missed a dose of medication. Possible responses were (1) *never*, (2) *very rarely/less than once a month*, (3) *occasionally/about once every other week*, (4) *fairly often/about once a week*, (5) *often/more than once a week but less than once a day*, and (6) *very often/daily.* Only patients responding at the 4 level or above (missed doses once a week or more) were enrolled into the study. These potential participants provided written informed consent for the study, including consent to an initial medical record abstraction. Initial eligibility as to diagnosis, receipt of HAART, and participation in other studies was verified through this abstraction. Of 170 participants invited to participate, 70 were ineligible (59% through screening question, 19% non-English speaking, 7% HAART not prescribed, 14% participation in another study, and 1% dementia), 21 refused participation, and 79 were enrolled, of whom 60 completed at least a baseline assessment. Eight of these participants either withdrew or were lost to follow-up after their baseline assessment.

Upon enrollment, participants were assigned code numbers previously randomized by computer, which assigned them into either the standard care condition ($n = 25$) or the intervention condition ($n = 27$). Participants included in the analysis were those for whom baseline and follow-up data were obtained and who, if randomized to the treatment condition, attended at least one session of that intervention. A subset of 33 participants provided complete data for this analysis. (Data on the other 19 subjects were not included due to their failure to complete one of the three assessment interviews.)

Demographic characteristics of the cohort ($n = 33$) are presented in Table 1. The mean age of participants was 39 years (range = 29-55, $SD = 6.88$), and 88% were male ($n = 29$). Racial/ethnic composition was as follows: 46% ($n = 15$) Black/African American, 30% ($n = 10$) White/Caucasian, 18% ($n = 6$) Latina or Latino/Hispanic, 3% ($n = 1$) Asian/Pacific Islander; 3% ($n = 1$) did not provide this information. Median monthly income was in the range of $501 to $1000, although the majority of the participants were not working (73%) ($n = 24$). Viral load (RNA copies per milliliter) at baseline was as follows: 33.3% ($n = 11$) had viral loads of 400 or less, 30.3% ($n = 10$) were in the 401 to 10,000 category, 15.2% ($n = 5$) were in the 10,001 to 50,000 category, and 9.1% ($n = 3$) had viral loads of more than 50,000; viral load data were missing from the medical charts for four (12.1%) participants. CD4+ counts ranged from 1 to 1,147 (mean =

340.14, *SD* = 291.32); CD4 count data were missing from the medical chart for five participants. Gender distribution for participants was similar to that for the clinic population (88% of participants were male whereas 82% of the clinic population was male). Ethnic distribution of the study participants varied somewhat from that of the clinic population: 44% were Latino/Hispanic, 30% were Black/African American, 24% were White/Caucasian, 1% were Native American, 1% were Asian/Pacific Islander, and 2% were "other." This variation was probably due to the exclusion of non-English-speaking patients. Demographic characteristics for the 19 participants not included in the analysis were similar to those for the participants included in the analysis with regard to age, gender, median monthly income, viral load, and CD4+ count. Racial/ethnic composition for excluded participants was as follows: 37% (*n* = 7) Black/African American, 16% (*n* = 3) White/Caucasian, 37% (*n* = 7) Latina or Latino/Hispanic, 5% (*n* = 1) Asian/Pacific Islander, and 5% (*n* = 1) mixed race.

Table 1. Demographics (*n* = 33)

Gender	
Male (29)	88%
Female (4)	12%
Ethnicity	
Black/African American	46%
White/Caucasian	30%
Latina or Latino/Hispanic	18%
Asian/Pacific Islander	3%
Did not provide	3%
Personal monthly income	
$0 to $500	9%
$501 to $1,000	12%
$1,001 to $2,000	6%
Not working	73%
Viral load (RNA copies/mL)	
≤ 400	33.3%
401 to 10,000	30.3%
10,001 to 50,000	15.2%
> 50,000	9.1%
NA	12.1%

Assessment Procedures

Assessment interviews were conducted with participants in both conditions at baseline, immediate postintervention (conducted about 7 to 8 weeks after baseline), and 3 months postintervention. Research assistants conducted interviews individually using computer-assisted personal interviewing; the research assistants administered each item to the participants and entered participant responses into the computer assessment program. Interviews included measures of self-report of adherence, strategies used to improve adherence, and barriers encountered. Other measures included cognitive/affective measures, measures of coping and self-efficacy, exploration of social support, reported health status, reported sexual risk behavior, reported substance use, knowledge about HIV/AIDS, and interactions with and confidence in care providers. The interviews took about 75 minutes to complete. They were usually conducted at the clinic where the participant was recruited, although occasionally they were conducted at participants' homes when they were unable to get to the clinic; both locations were approved for assessment through the institutional review board at the University of California, Los Angeles. Participants completed a daily medication diary for a 2-week period between the immediate postintervention assessment (IPIA) and the 3-month assessment points. Medical abstracts, documenting viral load, CD4 count, and current medications, were conducted at baseline and immediate postintervention.

Intervention Procedures

Volunteers were assigned computer randomized numbers, which assigned them to either the intervention or the standard care condition. Following randomization, baseline interviews were conducted. Four waves of the cognitive-behavioral intervention to improve medication adherence were conducted at the clinic from which participants were recruited. Intervention waves consisted of six to eight participants per condition and were of mixed gender; when women were part of an intervention, three women were assigned to each condition for that wave. Standard care was the regular care provided by the clinic as its normal policy. It consisted of the usual inquiries at regular appointments as to difficulty with adherence; those reporting problems received a single 30-minute consultation, had their medication schedule written down for them, and received no further intervention.

The intervention sessions were led by two facilitators, a cognitive-behavioral psychologist and a

psychiatric nurse, both experienced in working with HIV/AIDS patients. Facilitators followed a detailed content and procedures manual for the delivery of the intervention. Participants assigned to this condition attended an alternating series of five group and individual format sessions over 7 weeks. The content of the five intervention sessions was as follows: (a) group session in which information with regard to treatment of HIV/AIDS and the rationale for adherence to HAART, developed using input from focus groups conducted with HIV/AIDS patients, were reviewed and behavioral adherence strategies introduced; (b) individual session devoted to exercises in identifying barriers to adherence and to the development of an initial adherence plan, using behavioral strategies; (c) group session in which cognitive strategies were introduced, practiced, and incorporated into adherence plans; (d) individual session in which participants engaged in exercises designed to help them gain a sense of control over their own health care planning, identified information needs, and role-played ways to discuss issues with medical providers; and (e) group session devoted to modification and strengthening of individual adherence plans, anticipating challenges inherent in long-term adherence maintenance, anticipating relapse to nonadherence, and developing backup plans. All meetings ended with a homework assignment, which was a personal plan to improve adherence. Successes or difficulties with these plans were reviewed at the beginning of the next session.

Measures

Adherence

Self-report of specific adherence. Adherence to antiretroviral medications was assessed using a slightly modified version of the Adult AIDS Clinical Trials Group (ACTG) Adherence Baseline Questionnaire (Chesney & Folkman, 1994). Respondents were asked to report the following for each of their antiretroviral medications: (a) name of drug, (b) prescribed doses per day, (c) prescribed number of pills per dose, and (d) any special instructions with regard to food/liquid restrictions. Participants were then asked to state the number of pills and doses they took for each identified medication yesterday, the day before yesterday, and the previous Saturday. (To include only 1 weekend day, all interviews were conducted on Wednesdays, Thursdays, or Fridays.) Participants were also asked whether any of the doses taken on these days were taken off schedule, or late by 1 hour or more. Finally, respondents were asked to report overall, within the past month, how often they took their medications using a 6-item response scale (1 = *never*, 6 = *all the time*) and to identify the last time they missed taking any of their medications using a 6-item response scale (1 = *within the past week*, 6 = *never*). Support for the validity of the scale was reported by Hecht, Colfax, Swanson, and Chesney (1998), who found a correlation between self-report of nonadherence on this scale with viral load. Summary scoring procedures in clinical and ACTG studies calculate the percentage of medications taken versus a dichotomous measure of adherence or nonadherence (Chesney & Folkman, 1994). The calculation of percentage was used for this analysis of dose adherence. In addition, the average number of times participants reported being off schedule was calculated.

Coping strategies. Strategies for adherence, such as "used special carriers/containers to store and/or transport my antiretroviral medication" or "used a wrist alarm or some type of beeper to remind me of dose schedule" were rated on a 5-point scale of frequency employed (1 = *not at all*, 2 = *a little*, 3 = *somewhat*, 4 = *a lot*, and 5 = *does not apply/never tried it*). This strategic checklist, the Antiretroviral Medications Adherence Coping Strategies Scale, was developed by modifying a previous strategies coping scale (Murphy, Rotheram-Borus, & Marelich, in press), making each item specific to medication adherence. Five types of strategies were categorized based on content: behavioral, social support, provider related, spiritual, and cognitive. Overall reliability of the scale for this sample was high (α = .89). The total scale score, along with the five subscales, was examined for intervention effects in terms of number and category of strategies reported.

Social support. Social support was measured using the Social Provisions Scale (SPS) (Cutrona & Russell, 1987). The 24-item scale breaks down into subscales measuring six dimensions of social support (social

attachment, social integration, reassurance of worth, reliable alliance with others, guidance, and social nurturance), as well as an overall social support index. The SPS is supported by a large number of studies of its reliability and validity (Cutrona, 1989), including in past mental health intervention research with HIV-positive individuals (Kelly et al., 1993). Construct validity of the SPS has been demonstrated; comparison of interpersonal relationships with SPS scales has shown that attachment is significantly related to how satisfied individuals are with relationships (Russell, Cutrona, Rose, & Yurko, 1984). Reliability for the SPS subscales have been found to range from .65 (reliable alliance) to .76 (guidance); reliability for the entire measures has ranged from .87 to .90 (Cutrona & Russell, 1987). Internal consistency coefficient for this sample was .69.

Mental Health Indicators and Affective Status

Mental health. The RAND Mental Health Inventory (Stewart, Ware, Sherbourne, & Wells, 1992; Ware, Davies-Avery, & Brook, 1980) was administered as a measure of psychological distress and well-being. Factor analysis has indicated five subscales: general positive affect, emotional ties, anxiety, depression, and loss of behavioral or emotional control. These factors can be grouped into two higher order factors: psychological well-being and psychological distress (which are negatively correlated with each other, –.75). A sixth factor, life satisfaction, has also been identified (Ware et al., 1980). The scale was tested on a representative populations sample of 5,089 respondents in the RAND Health Insurance Study; internal consistency coefficients ranged from $\alpha = .83$ to $\alpha = .92$, with $\alpha = .96$ for the overall score. In this sample, the correlation between psychological well-being and psychological distress was –.59 ($p < .01$) and the internal consistency coefficient for the overall score was .73. Internal consistency coefficients for the subscales ranged from .57 to .90.

Depression. Depression was measured using the Center for Epidemiologic Studies–Depression (CES-D) scale (Radloff, 1977), a 20-item self-report symptom rating scale that assesses depression over the past week. The CES-D was developed through the Center for Epidemiologic Studies at the National Institute of Mental Health to measure depressive symptoms among adults in community surveys. The scale is widely used and has been used in numerous studies with HIV-infected patients (e.g., Cockram, Judd, Mijch, & Norman, 1999; Lyketsos et al., 1996; Revicki, Chan, & Gevirtz, 1998), with good previous internal consistency reliabilities of .87 and .88 (Roberts, Andrews, Lewinsohn, & Hops, 1990; Roberts, Lewinsohn, & Seeley, 1991). Convergent validity of the CES-D has been supported by correlations with other self-report scales designed to measure depression (i.e., Lubin, 1967) and discriminant validity by a low, negative correlation with social desirability (Radloff, 1977). Radloff (1977) reported reliability coefficients for the CES-D (α range = .84 to .90). Internal consistency reliability for this sample was .90.

Health-related anxiety. A short, 4-item scale was administered to assess health-related anxiety over the past week (Murphy, Moscicki, Vermund, & Muenz, 2000). This scale taps four domains that can be significantly affected by anxiety: sleep, appetite, social contact, and concentration at school or work. The scale has been previously used with an HIV-infected population, with a good internal consistency reliability of .85 (Murphy et al., 2001). Cronbach's alpha for this sample was .87.

Adherence efficacy. Selected items from the Adherence Self-Efficacy Scale (M. A. Chesney, personal communication, 1998) were administered to assess patients' confidence in their ability to carry out important health-related behaviors. The questionnaire was adapted from an assessment used in the adherence intervention trial of the Partnership in AIDS Clinical Trials. The scale consists of 33 items focusing on adherence efficacy in relation to an individual's treatment plan. Respondents are asked to rate their degree of confidence in their ability to do each of the tasks described using a 10-item response scale (0 = *cannot do at all* to 10 = *certain can do*). The following subscales of this measure were administered to participants: communication with clinical staff, sticking with the treatment schedule, and continuing with treatment. The internal consistency coefficient for this sample

was .90 for the overall score, .84 for communication with clinical staff, .86 for sticking with treatment schedule, and .86 for continuing with treatment.

Outcome expectancies. A 10-item measure of outcome expectancies related to adherence was administered to participants. Many of these questions were adapted from the Managing Your Medications Questionnaire (Willey et al., 2000). A 5-point Likert-type format, ranging from *strongly disagree* to *strongly agree*, was used. Four items assessed positive expectancies (e.g., taking medications as prescribed will help them stay well; taking medications will make them feel hopeful). Four items assessed negative expectancies (e.g., the medications do more harm than good). Two items focused on discussing problems with the medications with health care providers. The internal consistency coefficient for this sample was .69.

Analysis

Change scores (Allison, 1990; Huck & McLean, 1975; Sheeber, Sorensen, & Howe, 1996) were used to evaluate variations in adherence and affective status/mental health indicators across the baseline, IPIA, and 3-month follow-up assessments. Change scores were derived by subtracting latter assessments from earlier ones (see Table 2 for mean scores and Table 3 for change scores). Hence, three change scores were derived for the analysis variables: a change score between baseline and IPIA, between baseline and 3-month follow-up, and between IPIA and 3-month follow-up. Independent-samples *t*-tests were used to test the efficacy of the intervention by comparing the control group to the intervention group on self-reported adherence, coping strategies and social support, mental health indicators and affective status, and outcome expectancies across time (see Table 4).

Results

Self-Report of Adherence

Self-reported schedule adherence assessed the number of times participants were off schedule in their daily medication-taking routine. Table 2 shows the mean schedule adherence scores for the treatment group and control group across the three time points (baseline, IPIA, and 3-month follow-up). From IPIA to 3-month follow-up, there was a trend for the treatment group to be on schedule more often than the control group, $t(29) = 1.95$, $p = .06$ (see Table 4). Self-reported dose adherence was examined by comparing participants' pill-taking habits over 3 days (yesterday, the day before yesterday, and the previous Saturday). No difference was found between the treatment and control groups over time. Interestingly, self-reported adherence to dose seemed to increase over time for both groups.

Coping Strategies/Social Support

The Antiretroviral Medication Adherence Coping Strategies Scale was used to assess how participants coped with the difficulties involved in taking antiretroviral medications. The overall scale score, along with the five subscales (behavioral, social, provider, spiritual, and cognitive), was examined for intervention effects. No differences were found between the treatment and control groups on the number of coping strategies used. The control group showed a significant decline in use of behavioral strategies from baseline to IPIA and baseline to 3-month follow-up, $t(19) = -3.02$, $p = .01$, and $t(19) = -3.15$, $p = .01$, respectively, as well as a significantly greater decline in the use of cognitive strategies from baseline to IPIA and baseline to 3-month follow-up, $t(30) = -2.56$, $p = .02$, and $t(30) = -2.06$, $p = .04$, respectively.

On the SPS, although participants generally reported positive feelings of social support from their relationships with others (Table 2), the treatment group reported an increase in feelings of support whereas the control group reported a decline from baseline to IPIA, $t(31) = -2.13$, $p = .04$.

Mental Health Indicators and Affective Status

On the RAND Mental Health Inventory over time (baseline to IPIA and baseline to 3-month follow-up), the treatment group reported an increase on the life satisfaction subscale whereas the control group reported a decline, $t(31) = -2.10$, $p = .04$, and $t(31) = -2.32$, $p =$

Table 2. Descriptive Statistics for Dependent Measures

	Treatment							Control						
		Baseline		IPIA		3-Month Follow-Up			Baseline		IPIA		3-Month Follow-Up	
Time Point Group	***N***	***M***	***SD***	***M***	***SD***	***M***	***SD***	***N***	***M***	***SD***	***M***	***SD***	***M***	***SD***
Adherence														
Self-report dose adherence	17	0.69	0.41	0.87	0.30	0.86	0.33	14	0.62	0.46	0.87	0.28	0.83	0.36
Self-report schedule adherence	17	3.71	4.65	1.82	2.77	0.35	0.86	16	3.93	4.99	1.63	2.16	3.06	4.82
Adherence efficacy														
Communicate with clinical staff	17	58.47	11.50	66.06	12.11	70.06	7.21	16	60.06	16.91	63.19	17.99	63.75	11.74
Sticking to treatment schedule	17	67.35	18.96	78.06	17.87	82.94	16.14	16	62.63	19.71	63.75	19.38	73.69	15.78
Continue with treatment	17	58.00	13.06	63.29	11.42	67.41	7.75	16	60.69	11.75	58.69	12.66	60.13	12.12
Total adherence efficacy Score	17	202.76	37.90	227.65	36.21	240.53	29.61	16	201.94	39.63	203.00	45.34	215.38	37.11
Coping strategies/social support														
Behavioral	9	37.89	6.99	38.11	7.24	38.44	4.42	12	42.00	6.67	33.42	5.50	33.83	5.54
Social	17	24.47	5.64	21.00	6.86	20.82	6.97	15	19.47	4.37	17.53	5.44	18.53	5.63
Provider	17	7.00	3.28	7.71	3.46	6.59	2.96	15	6.53	2.39	6.47	2.13	6.33	3.20
Spiritual	17	8.29	3.67	9.24	3.95	8.71	3.16	15	6.53	3.42	7.00	3.57	7.20	3.76
Cognitive	17	33.41	5.00	33.00	6.67	29.59	6.30	15	35.60	5.46	27.00	6.82	24.67	8.07
Total coping strategies score	17	26.52	6.94	27.35	7.75	25.82	7.35	16	23.75	6.91	24.44	8.29	21.81	11.02
Social Provisions Scale	17	71.53	9.25	73.71	10.66	74.06	11.61	16	74.44	7.24	71.13	11.63	73.56	9.58
Psychological factors														
Behavioral/emotional control	17	22.47	7.88	21.71	7.59	20.29	8.36	16	19.44	6.24	21.25	7.35	20.63	5.83
General positive affect	17	39.47	9.33	38.18	9.33	41.06	9.22	16	39.31	10.12	36.06	10.85	37.94	7.51
Emotional ties	17	8.06	2.97	7.76	2.46	8.18	2.40	16	7.75	1.91	7.25	2.52	7.50	1.97
Life satisfaction	17	3.94	1.30	4.12	1.36	4.47	1.28	16	4.13	1.09	3.31	1.62	3.63	1.36
Psychological distress	17	45.35	13.63	41.12	14.13	40.82	15.29	16	37.50	12.51	40.00	15.64	39.13	10.51
Depression	17	11.58	3.73	9.76	3.42	10.12	4.14	16	9.19	3.49	9.56	4.18	10.19	3.10
Psychological well-being	17	54.82	12.80	54.00	12.68	57.47	12.94	16	55.19	13.09	50.06	14.52	52.38	9.49
Anxiety	17	27.24	8.62	25.12	9.89	24.82	9.75	16	22.88	8.20	24.31	9.25	22.81	6.35
Total MHI score	17	127.12	15.85	122.35	14.91	122.82	14.13	16	118.13	11.97	116.81	14.79	118.00	10.69
CES-D	17	41.18	10.59	38.71	12.96	37.65	14.30	16	33.75	11.05	38.38	11.87	36.13	11.53
Health-related anxiety	17	8.47	4.09	8.76	4.91	7.88	4.41	16	6.88	4.18	6.06	2.46	7.31	4.27
Outcome expectancies	16	35.19	6.28	36.31	5.00	37.56	5.74	16	36.88	6.42	36.81	4.69	36.81	4.89

NOTE: IPIA = immediate postintervention assessment, MHI = Mental Health Index, CES-D = Center for Epidemiologic Studies–Depression.

.03, respectively. The same pattern appeared for the behavioral and emotional control subscales. Between baseline and 3-month follow-up, there was a trend for the treatment group to report feeling a greater sense of behavioral and emotional control, whereas the control group reported decreases, $t(31) = 1.92$, $p = .06$. On the CES-D scale, which was used as an additional measure of depression, there was also a trend for the treatment group to report a decrease in feeling depressed as compared to an increase in depression by the control group between baseline and IPIA, $t(31) = 1.70$, $p = .10$. No differences were found between the treatment and control groups across time for the measure of health-related anxiety.

Adherence Efficacy

The treatment group reported an increase in overall adherence efficacy between baseline and 3-month follow-up, $t(31) = –2.13$, $p = .04$, as well as an increase in being able to communicate with clinical staff and willingness to continue with treatment despite outside pressures, $t(31) = –2.13$, $p = .04$, and $t(31) = –2.10$, $p = .04$, respectively.

Outcome Expectancies

No differences were found between the treatment and control groups on outcome expectancies over

Table 3. Descriptive Statistics for Change Scores

	Treatment							Control						
		BL-IPIA		IPIA-FU3		BL-FU3			BL-IPIA		IPIA-FU3		BL-FU3	
Time Point Group	***N***	***M***	***SD***	***M***	***SD***	***M***	***SD***	***N***	***M***	***SD***	***M***	***SD***	***M***	***SD***
Adherence														
Self-report dose adherence	17	0.18	0.35	–0.05	0.34	0.18	0.48	14	0.25	0.45	–0.04	0.45	0.21	0.41
Self-report schedule adherence	17	–1.88	5.09	–1.47	3.04	–3.35	4.74	16	–2.31	5.75	1.44	5.30	–0.88	4.38
Adherence efficacy														
Communicate with clinical staff	17	7.59	15.42	4.00	7.48	11.59	12.83	16	3.13	11.66	0.56	10.40	3.69	7.70
Sticking to treatment schedule	17	10.71	18.22	4.88	11.89	15.59	16.20	16	1.13	23.45	9.94	18.62	11.06	17.30
Continue with treatment	17	5.59	12.25	4.12	9.72	9.41	12.55	16	–2.00	14.10	1.44	12.66	–0.56	14.78
Total adherence efficacy score	17	24.88	40.48	12.88	21.08	37.76	35.09	16	1.06	43.49	12.38	31.76	13.44	30.29
Coping strategies/social support														
Behavioral	9	0.22	6.44	0.33	6.52	0.56	6.17	12	–8.58	6.73	0.42	3.65	–8.17	6.37
Social	17	–3.47	4.05	–0.18	4.98	–3.65	4.91	15	–1.93	6.20	1.00	5.62	–0.93	4.48
Provider	17	0.71	3.64	–1.12	2.03	–0.41	3.68	15	–0.07	2.89	–0.13	2.70	–0.20	2.48
Spiritual	17	0.94	2.88	–0.53	2.35	0.41	2.62	15	0.47	2.36	0.20	1.57	0.67	2.19
Cognitive	17	–0.41	8.33	–3.41	4.35	–3.82	8.43	15	–8.60	9.80	–2.33	3.77	–10.93	11.09
Total coping strategies score	17	0.82	5.98	–1.53	6.20	–0.71	5.41	16	0.69	7.59	–2.63	10.68	–1.94	8.94
Social Provisions Scale	17	2.18	7.46	0.35	6.88	2.53	8.72	16	–3.31	7.33	2.44	7.58	–0.88	9.01
Psychological factors														
Behavioral/emotional control	17	–0.76	6.37	–1.41	6.84	–2.18	5.27	16	1.81	6.65	–0.63	6.42	1.19	4.76
General positive affect	17	–1.29	8.60	2.88	6.86	1.59	7.38	16	–3.25	9.46	1.88	6.45	–1.38	7.23
Emotional ties	17	–0.29	1.86	0.41	1.91	0.12	1.87	16	–0.50	2.50	0.25	2.46	–0.25	2.52
Life satisfaction	17	0.18	1.29	0.35	1.50	0.53	0.94	16	–0.81	1.42	0.31	1.74	–0.50	1.55
Psychological distress	17	–4.24	11.12	–0.29	10.90	–4.53	12.88	16	2.50	11.97	–0.88	14.12	1.63	7.07
Depression	17	–1.82	2.70	0.35	3.06	–1.47	3.41	16	0.38	4.54	0.63	4.03	1.00	2.76
Psychological well-being	17	–0.82	10.66	3.47	9.41	2.65	9.03	16	–5.13	12.20	2.31	9.50	–2.81	9.25
Anxiety	17	–2.12	7.92	–0.29	7.22	–2.41	8.02	16	1.44	6.26	–1.50	7.88	–0.06	5.13
Total MHI score	17	–4.76	14.30	0.47	10.01	–4.29	14.03	16	–1.31	12.13	1.19	12.98	–0.13	9.76
CES-D	17	–2.47	11.16	–1.06	10.99	–3.53	11.29	16	4.63	12.88	–2.25	11.75	2.38	11.45
Health-related anxiety	17	0.29	4.13	–0.88	4.33	–0.59	4.47	16	–0.81	3.23	1.25	3.47	0.44	1.82
Outcome expectancies	16	1.13	6.62	1.25	5.12	2.38	3.14	16	–0.06	5.30	0.00	3.74	–0.06	5.64

NOTE: BL = baseline, IPIA = immediate postintervention assessment, FU3 = 3-month follow-up, MHI = Mental Health Index, CES-D = Center for Epidemiologic Studies–Depression.

time. As can be seen in Table 2, neither the treatment group participants nor the control group participants strongly agreed or disagreed with statements referring to their expectations of how antiretroviral medications would help them.

Discussion

In this small pilot trial, participants who received the intervention showed a trend toward increased adherence to their antiretroviral medication schedule compared to the standard care control group. Given the necessity of continuous coverage of these medications to prevent the development of viral resistance, this is an important benefit for these patients. However, the intervention did not appear to improve adherence to dose. Because improving adherence to medication dosage was a main goal of the intervention, this finding is disappointing. It is interesting to note that despite the fact that the intervention participants were significantly more likely to be using behavioral strategies following participation in the intervention, and also significantly more likely to be using cognitive strategies, these efforts were not sufficient to translate into improved dose adherence.

The intervention was also designed to improve patient-physician communication, social support, and acceptance of the need for taking medication. Results indicate that the intervention was effective in these

areas. That is, there were a number of secondary benefits of intervention participation. First, intervention participants reported significantly higher self-efficacy with regard to communication with clinic staff following the intervention compared to the standard care group. Second, the patients who participated in the intervention had significantly higher self-efficacy scores for continuing treatment despite obstacles compared to the control group. Changing behavior requires a strong sense of efficacy that one can exercise personal control; when people lack self-efficacy, they do not manage situations effectively even if they are knowledgeable and have the requisite skills. Therefore, unless people believe that they can produce a desired effect by their own actions, they have little motivation to act or persevere in the face of obstacles. Efficacy beliefs influence the course of action individuals choose, how much effort they put into the course of action, how long they persevere in the face of barriers, and the level of accomplishment they realize (Bandura, 1999). Thus, these results indicate that the intervention participants are more likely to continue to try to improve their medication adherence. A third benefit of program participation was that the intervention participants reported significantly increased levels of social support immediately following the intervention program. This may be a function of having attended the three group sessions with other patients who were experiencing similar problems with regard to antiretroviral adherence. They may also have felt strong support through their interactions with the cognitive-behavioral psychologist and the nurse at all of the sessions. Fourth and finally, the intervention participants reported significantly higher life satisfaction following the intervention than did the standard care group, although there were no significant differences for the other mental health subscales or for the depression or health-related anxiety scales.

Our intervention did not result in an improvement in adherence to dosage greater than that observed in our control group. It is possible that being in a study and having repeated assessments influenced both the control and intervention groups; however, although both groups improved on this measure, it is also important to note that neither group's reported adherence to dosage approaches that thought to be required in order to achieve adequate viral suppression. The question of why the intervention was not successful in improving adherence to dose is an important one, given that a cognitive-behavioral approach that has been shown to work in similar settings for other health behaviors was used. One explanation for the null results may be that extraneous factors beyond what was measured had some effect (Lipsey, 1988). Because both the intervention and control groups showed increases in adherence to dose over time, this suggests that (a) the intervention had no effect, yet something extraneous to both groups led to the increases, or (b) the intervention did have an effect, and something unique also occurred to the control group, thus leading to similar increases in adherence. Cook and Shadish (1994) noted that in randomized experiments, both control and intervention groups need to be closely monitored, further stating that treatments can "diffuse," especially in field contexts. Whether this occurred in the current study is unknown.

An additional possibility to be explored relates to the role of self-efficacy and social support in sustaining adherence. Our failure to find between-groups differences in improvement in adherence to dose occurred not because group participants did not improve their adherence but because both groups improved equally. The repeated assessments may have served as an intervention. That is, the improvements in both groups may have arisen from participants' awareness that their adherence levels were being observed—an effect that is frequently found to be relatively short in duration. Because self-efficacy and social support for taking medication have been found to be positively related to self-reported treatment adherence, and because our follow-up was relatively brief (3 months), additional research investigating the role of treatment-induced improvements in self-efficacy and social support for taking medication in sustaining long-term adherence is needed.

Obviously, one major limitation of this study is the small sample size; this was a pilot trial of the intervention. Despite limitations, the results of this study have several implications for nursing. This multidisciplinary intervention, which used a cognitive-behavioral psychologist and a nurse practitioner to co-facilitate the intervention sessions, resulted in improvement in self-efficacy for patient-physician communication, social support, and some mental health indicators (e.g., life satisfaction, self-efficacy to continue treatment despite obstacles). It is likely that the interven-

Table 4. Results of Independent-Samples *t* Tests

		BL-IPIA			IPIA-FU3			BL-FU3		
Time Point	***N***	***t***	***df***	***p***	***t***	***df***	***p***	***t***	***df***	***p***
Adherence										
Self-report dose adherence	31	0.50	29	.62	–0.23	29	.82	0.23	29	.82
Self-report schedule adherence	33	–0.23	31	.82	1.95	31	.06*	1.56	31	.13
Adherence efficacy										
Communicate with clinical staff	33	–0.93	31	.36	–1.10	31	.28	–2.13	31	.04**
Sticking to treatment schedule	33	–1.32	31	.20	0.94	31	.36	–0.78	31	.44
Continue with treatment	33	–1.59	31	.12	–0.69	31	.50	–2.10	31	.04**
Total adherence efficacy score	33	–1.63	31	.11	–0.05	31	.96	–2.13	31	.04**
Coping strategies/social support										
Behavioral	21	–3.02	19	.01**	0.04	19	.97	–3.15	19	.01**
Social	32	0.84	30	.41	0.63	30	.54	1.63	30	.12
Provider	32	–0.66	30	.52	1.18	30	.25	0.19	30	.85
Spiritual	32	–0.51	30	.62	1.02	30	.32	0.30	30	.77
Cognitive	32	–2.56	30	.02**	0.75	30	.46	–2.06	30	.04**
Total coping strategies score	33	–0.06	31	.96	–0.36	31	.72	–0.48	31	.63
Social Provisions Scale	33	–2.13	31	.04**	0.83	31	.41	–1.10	31	.28
Psychological factors										
Behavioral/emotional control	33	1.14	31	.26	0.34	31	.74	1.92	31	.06*
General positive affect	33	–0.62	31	.54	–0.43	31	.67	–1.16	31	.25
Emotional ties	33	–0.27	31	.79	–0.21	31	.83	–0.48	31	.64
Life satisfaction	33	–2.10	31	.04**	–0.07	31	.94	–2.32	31	.03**
Psychological distress	33	1.68	31	.11	–0.13	31	.90	1.69	31	.11
Depression	33	1.70	31	.10*	0.22	31	.83	2.28	31	.03**
Psychological well-being	33	–1.08	31	.29	–0.35	31	.73	–1.72	31	.10*
Anxiety	33	1.42	31	.16	–0.46	31	.65	1.00	31	.33
Total MHI score	33	0.75	31	.46	0.18	31	.86	0.99	31	.33
CES-D	33	1.70	31	.10*	–0.30	31	.77	1.49	31	.15
Health-related anxiety	33	–0.85	31	.40	1.56	31	.13	0.85	31	.40
Outcome expectancies	32	–0.56	30	.58	–0.79	30	.44	–1.51	30	.14

NOTE: BL = baseline, IPIA = immediate postintervention assessment, FU3 = 3-month follow-up, CES-D = Center for Epidemiologic Studies–Depression.
*$p < .10$. **$p < .05$.

tion sessions that focused on patient-physician communication were strongly enhanced by having a nurse co-facilitate, as patients would see this person as a credible source for learning how to approach and interact with health care providers. Also, many of the components of the intervention could be successfully implemented in health care clinics by nurses when patients are having trouble adhering to their antiretroviral regimen.

Although this intervention program did not successfully improve antiretroviral medication adherence to dosage, it did have significant beneficial outcomes in a number of other areas that are crucial in order for a patient to be successful with a medication regimen. Further work needs to be conducted to clearly identify the components of this intervention that resulted in improved adherence to medication schedule, self-efficacy for patient-physician communication, and continuing treatment. In addition, replication of these findings needs to occur. Future work in this area will need to determine even stronger behavioral interventions specifically oriented to improving patient adherence to medication dose. It is possible that the small sample size in this study precluded the discovery of small intervention effects. As Maddock and Rossi (2001) recently noted, not only do intervention studies typically have much less power to detect effects than nonintervention studies, but studies examining small effects are often underpowered—and most intervention effects in health psychology are small. It is

possible that a larger trial of this intervention would more clearly illustrate the benefits and limitations of the intervention.

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