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A Randomized Controlled Trial of a Peer Support Intervention Targeting Antiretroviral Medication Adherence and Depressive Symptomatology in HIV-Positive Men and Women

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Abstract

Objective—To determine the efficacy of a peer-led social support intervention involving support groups and telephone contacts compared with standard clinical care to enhance antiretroviral medication adherence.

Design—Randomized controlled trial with follow-up. Participants were 136 HIV-positive indigent mainly African American and Puerto Rican men and women recruited from an outpatient clinic in the Bronx, New York. The 3-month intervention was delivered by other HIV-positive clinic patients trained in addressing barriers to adherence and sensitively providing appraisal, spiritual, emotional, and informational adherence-related social support.

Main outcome measures—Medical chart-abstracted HIV–1 RNA viral load, antiretroviral adherence according to electronic drug monitoring and participant self-report, and social support and depressive symptomatology. All assessments conducted at baseline, 3 months, and 6 months.

Results—Intent-to-treat and as-treated analyses indicated no between-conditions intervention effects on the primary outcome of HIV–1 RNA viral load or any of the secondary outcomes at immediate postintervention or follow-up. Post hoc analyses within the intervention condition indicated greater intervention exposure was associated with higher self-reported adherence, higher social support, and lower depressive symptomatology at follow-up, even after controlling for baseline adherence.

Conclusion—Null findings, consistent with the limited literature on efficacious highly active antiretroviral therapy (HAART) adherence interventions, may be due to insufficient exposure to the intervention, its low intensity, or the nature of the sample—a heterogeneous HAART-experienced group of patients with high levels of substance use and multiple other competing stressors. Overall, findings highlight the need for more comprehensive and intensive efforts to battle nonadherence.

Keywords

HIV/AIDS; HAART; adherence; social support; depression

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> Nonadherence to therapies for chronic illness is a long-standing problem that is recognized as one of the most perplexing problems in health care today. (Reynolds, 2004, p. 207)

Nonadherence to medical provider directives and prescribed medication regimens is a common and serious problem that has frustrated care providers, negatively impacted physical and mental health, and burdened society in terms of staggering economic costs (Osterberg & Blaschke, 2005). Specifically, nonadherence to the 1.8 billion prescriptions written annually in the United States (Besch, 1995) is about 50% (range = 15%–93%; Haynes, Mc-Kibbon, & Kanani, 1996) and is even higher among individuals with chronic illnesses (Cramer, Mattson, Prevey, Scheyer, & Ouellette, 1989). Yearly monetary costs exceed $100 billion (Task Force for Noncompliance, 1994).

Nonadherence is particularly problematic with highly active antiretroviral therapy (HAART), the medical standard of care for the treatment of people living with HIV/AIDS. Multiple studies have shown that nonadherence independently predicts the development of drug resistance as well as opportunistic infections and hospital admissions (Bangsberg et al., 2003; Bartlett, 2002). Data suggest that viral suppression is directly linked to adherence, with optimal results most likely at extremely high levels of adherence (Bartlett, 2002; Paterson et al., 2000). A commonly cited goal is 95% adherence, which is the equivalent of missing fewer than three doses a month on a twice daily regimen. Few patients can achieve or maintain this benchmark for extended periods. Indeed, a conservative estimate of average HAART adherence among outpatients is 80% (Hinkin et al., 2004).

The potential contribution of behavioral science to health care is probably nowhere greater than in the area of understanding and mitigating medical nonadherence. However, thus far the empirical literature on the efficacy of interventions to increase adherence is scant and disappointing (Haynes et al., 1996; McDonald, Garg, & Haynes, 2002). Reviewers have concluded, “Current methods of improving medication adherence for chronic health problems are mostly complex, labor-intensive, and not predictably effective” (McDonald et al., 2002, p. 2868). With respect to interventions to increase adherence to antiretroviral therapy, the literature is even more limited (Simoni, Frick, Pantalone, & Turner, 2003; Simoni, Pantalone, Frick, & Turner, 2005). Two recent meta-analytic reviews suggest behavioral interventions can be effective in enhancing antiretroviral adherence and decreasing HIV–1 RNA viral load (Amico, Harman, & Johnson, 2006; Simoni, Pearson, Pantalone, Crepaz, & Marks, 2006), but they offer little guidance as to the most efficacious strategies.

In developing an intervention to enhance antiretroviral adherence, we focused on the potential benefits of social support. Research that has examined the effect of manipulating social support in medical populations has found that increased social support leads to improvements in adherence (Becker & Green, 1975; Doherty, Schrott, Metcalf, & Iasiello-Vailas, 1983; Kirscht, Kirscht, & Rosenstock, 1981; Levy, 1983). Among HIV-positive individuals specifically, social support is related to adherence (Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; Gordillo, Amo, Soriano, & Gonzalez-Lahoz, 1999; Remien

et al., 2003), although no published reports of interventions among HIV-positive individuals have focused on the effects of bolstering levels of support.

Another important factor in our decision to target social support is that interventions based on social support—and peer support in particular—are practical, feasible, cost effective, and potentially highly exportable. These are key considerations in resource-limited settings, including developing nations, where the roll-out of HAART is advancing rapidly. In the cancer literature, peer support interventions have been shown to have long-term benefits in several domains of psychosocial functioning such as vitality, social functioning, and overall mental health (Helgeson, Cohen, Schulz, & Yasko, 1999), although these findings are not consistent across interventions (e.g., Campbell, Phaneuf, & Deane, 2004). AIDS-service organizations have implemented peer support programs since the early days of the epidemic, but no one has systematically evaluated their effectiveness.

Our intervention is based on a working model of how social support enhances adherence (Simoni, Frick, & Huang, 2006; Simoni, Frick, Lockhart, & Liebovitz, 2002). The model presumes the effects of social support on adherence are mediated by cognitive and affective variables, primarily negative emotional states such as depressed mood. It emphasizes the importance of appraisal, emotional, and informational support.

Depressive symptomatology is a potentially potent intervention target because of its consistent association with nonadherence among HIV-positive individuals (Chesney et al., 2000; Gordillo et al., 1999; Paterson et al., 2000; Treisman, Angelino, & Hutton, 2001). Moreover, depression is the most frequently diagnosed psychiatric condition in the HIV-positive population (Treisman et al., 2001). Estimates suggest that between 18%–60% of people living with HIV meet criteria for depression sometime during their illness (Gordillo et al., 1999; Orlando et al., 2002; Treisman et al., 2001). Individuals struggling with depression may lack the physical and mental energy and sustained motivation to maintain high levels of adherence (Tucker et al., 2004). In addition, depressed patients frequently have feelings of hopelessness directed toward themselves and their future and thus may not fully appreciate the association between medication adherence and improved health outcomes. Finally, individuals struggling with both HIV and depression may be more prone to cognitive impairment or forgetfulness which additionally impede adherence.

Research addressing the effects of social support on depressive symptomatology in HIV-positive individuals has revealed that social support is correlated with depressive symptomatology not only cross-sectionally but longitudinally as well (Hays, Turner, & Coates, 1992; Siegel, Karus, & Raveis, 1997), highlighting “the potential value of interventions designed to enhance social support in an effort to reduce depressive symptomatology” (Siegel et al., 1997, p. 236). Social support, particularly in the form of emotional support (i.e., listening, caring, and empathic companionship) may decrease depressive symptomatology by encouraging adaptive coping or increasing self-esteem (Veiel & Baumann, 1992).

In the present study, we evaluated a peer support intervention grounded in our social support model of adherence that posits a central role for depressive symptomatology in

nonadherence. The randomized controlled trial (RCT) involved men and women living with HIV/AIDS in the Bronx, New York, and included an a priori primary clinical outcome and the secondary outcomes of adherence, social support, and depressive symptomatology.

Method

Participants

Sociodemographic and other descriptive information on the 136 participants enrolled at baseline is provided by study condition in Table 1. Note that the sample comprised mainly African American and Puerto Rican men and women of low socioeconomic status. Initial calculations, based on .83 power to detect a significant difference (p = .05, two-tailed), had indicated 75 patients were required for each study group.

Procedures

This RCT was conducted at the adult HIV primary care outpatient clinic at Jacobi Medical Center, a public institution serving mainly indigent, ethnic minority individuals in the Bronx, New York. Graduate psychology student research assistants (RAs) consulted with clinic staff and referred to patient medical records to assess the eligibility of patients in the clinic waiting room according to the following criteria: at least 18 years of age, proficient in English, currently on a prescribed HAART regimen, and who were without dementia or psychosis. Participants could be HAART naive or experienced, and there was no CD4 count or HIV–1 RNA viral load inclusion criteria. RAs attempted to approach all eligible patients between May 2000 and March 2002. Interested patients were scheduled for a later baseline appointment to give consent, be randomly assigned to either the peer support intervention or standard of care (SOC), and given a 50-min interviewer-administered baseline interview. Random assignment to condition was based on a computer-generated allocation sequence prepared by an external statistician. Allocation concealment involved the use of sequentially numbered, opaque, sealed envelopes containing the group assignment, which the RAs opened at the moment of randomization after participants were consented and enrolled.

Electronic drug monitors (EDM; i.e., the Medication Event Monitoring System; http://www.aardex.ch) were provided to all participants for the duration of the trial. EDM technology consists of a plastic pill vial and modified cap containing a microprocessor capable of recording the precise date and time of each vial opening as a presumptive dose. Each participant was given one EDM to use with the most frequently dosed medication. All participants continued to receive medical care at the clinic and were asked to return for follow-up interviews at 3 and 6 months, at which time EDM data were uploaded, HIV–1 RNA viral load data were extracted from patient medical records and participants were reinterviewed. Due to the nature of the intervention, participants could not be uninformed of the study condition; however, RAs conducting the follow-up assessments were blinded to the study condition of the interviewees. Participants were reimbursed $20, $25, and $30, respectively, for the assessment interviews, with a $25 bonus if they completed all three assessments and returned the EDM. Tracking efforts included extensive, unscripted reminder phone calls and mailed correspondence when necessary.

Intervention

Current clinic patients who were HIV-positive and on HAART served as "peers" who provided support in the peer support intervention (see Marino, Simoni, & Silverstein, 2007). Medical providers in the clinic assisted study staff in identifying peers who reported consistently high levels of adherence, attended clinic appointments regularly, were socially skilled, and were able to participate in initial training and ongoing supervision. During two separate training sessions (each approximately 16 hr over 4 half-days), research staff trained a total of 12 peers how to assess for negative affective states and other barriers to adherence and to sensitively provide appraisal, spiritual, emotional, and informational social support. Other topics covered in the training included an overview of HIV and HAART, setting appropriate limits on the peer relationship, overcoming potential barriers to the acceptance of support, harm reduction approaches to substance use, making appropriate referrals for medical inquiries, and strategies for working with diverse participants. Peers received $20–$30 twice monthly as an incentive for their involvement, based on the number of participants (1, 2, or 3) they were assigned.

The 3-month peer support intervention consisted of two parts: six twice-monthly 1-hr group meetings at the clinic of all peers and actively enrolled participants (i.e., "peer meetings") in addition to weekly phone calls from peers to participants who were assigned to them individually by research staff on the basis of availability and presumed compatibility (i.e., whenever possible, an effort was made to match peers to participants on the basis of ethnicity, sex, and sexual orientation). In the group setting, participants had the opportunity to spend face-to-face time with their assigned peer, as well as meet the other peers and participants, with the goal of benefiting from the discussion of the shared experiences of the group. The primary themes of the meeting were identifying barriers to HAART adherence and generating and troubleshooting problem-solving strategies to overcome them. Other themes that often emerged were life issues related to adherence, including HIV status disclosure, sexual and romantic relationships, substance use, and struggles with mental health issues. One RA coordinated the groups (e.g., arranged the room and provided refreshments) and facilitated discussion (e.g., refocused the discussion on adherence-related topics when appropriate) but otherwise refrained from interfering with the group process and the exchange of support among peers and participants, resulting in predominantly peer-led groups. Participants received no reimbursement for attending the sessions beyond $3 for the cost of public transportation.

Between group meetings, peers were instructed to call each of their study participants thrice weekly to provide more in-depth, one-on-one attention and feedback. Phone calls also were better suited for participants with confidentiality concerns and those who had difficulty traveling to the clinic or had scheduling conflicts with the set meeting times.

To preserve intervention fidelity, peers were tested at the end of the training to ensure they acquired competency in their responsibilities. Peers also received ongoing supervision during twice-monthly group meetings and regularly scheduled telephone checkins. In addition, they completed a one-page log for each telephone and face-to-face contact with a participant.

SOC participants were given social and mental health referrals when requested. Otherwise, SOC participants received no additional adherence assistance beyond the clinic's typical offerings, which consisted of consultation with primary providers as part of routine medical care. In this preliminary investigation of the effects of peer support, no attention control component was included. The ability to determine whether efficacy was due to either differential intensity or differential intervention content was relegated to a future investigation.

Measures

Clinical outcome—RAs extracted the most recently recorded HIV–1 RNA viral load from patient medical records at each of the three assessment periods. As the data were not normally distributed, we conducted a log transformation and used the transformed values in all further analyses.

Adherence—Adherence was assessed at baseline as well as at 3 and 6 months with a modified version of the widely used Adult AIDS Clinical Trials Group Adherence to Antiretrovirals Instrument (Chesney et al., 2000). For each medication prescribed, patients reported for each of the last 3 days the number of doses taken. We computed an adherence variable that consisted of the percentage of doses taken (according to self-report) over those prescribed (according to medical record) for the past 3 days. In addition, with EDM data, we calculated a similar variable for the observed drug during the 4-week and 3-month periods preceding the 3- and 6-month assessments (no EDM data were available at baseline, when the EDM caps were distributed).

Social support—Social support was measured with a modified version of the UCLA Social Support Inventory (Schwarzer, Dunkel-Schetter, & Kemeny, 1994). Participants were asked to indicate how satisfied they were from 1 (*very dissatisfied*) to 4 (*very satisfied*) with various types of support they had received from other people (i.e., "family, friends, peers, and doctors or other clinic staff") in the past 30 days. The scale has shown strong reliability and validity in an HIV-positive sample (Simoni & Ng, 2000); in the present sample, Cronbach's alpha for the four items was .75.

Depressive symptomatology—Participants completed the Centers for Epidemiological Studies Depression Scale (Radloff, 1992), a nondiagnostic screening measure for examining the prevalence of nonspecific psychological distress in community samples. The scale's 20 items assessing depressive symptomatology in the previous week (e.g., "I was bothered by things that usually don't bother me") are rated from 0 (rarely or none of the time/less than one day in the past week) to 3 (*most or all of the time/5–7 days in the past week*). The scale has demonstrated validity, internal consistency, and test–retest reliability (8-week interval, r = .59) (Radloff, 1992). In this study alpha was equal to .89.

Results

Flow of Participants

A significant minority of patients approached was ineligible for participation either because they were currently not prescribed HAART or were severely psychologically or cognitively impaired. Fifty-three percent of eligible patients approached declined to participate. The primary reasons cited for refusal were lacking interest, being too busy, having transportation difficulties that made it difficult to accommodate the additional study-related clinic visits, and being asocial or feeling uncomfortable in groups. Among the 71 participants randomly assigned to the peer intervention, 36 (51%) attended at least two peer meetings, 54 (76%) completed the 3-month assessment, and 59 (83%) completed the 6-month assessment. Retention among the 65 participants in SOC was not statistically different: Numbers were 51 (78%) at 3 months and 57 (88%) at 6 months.

Baseline comparison of participants in the peer support intervention and SOC demonstrated that randomization was successful: No differences were found on any sociodemographic or outcome variable except for satisfaction with social support, which was slightly higher among participants randomized to the SOC condition, $t(134) = 2.06$, $p < .05$. Because analyses of intervention effects controlling versus not controlling for this baseline variable did not differ significantly, we report only the unadjusted results.

Adherence Levels

Overall, adherence levels were initially low and decreased over time, with self-reported 3-day adherence overall averaging 78% at baseline, 80% at 3 months, and 72% at 6 months (see Table 1). These levels appear even more deficient when analyzed in terms of the percentage of participants who achieved the 95% benchmark: Only 59% of participants at baseline, 65% at 3 months, and 61% at 6 months reported taking 95% or more of their prescribed medications over the previous 3 days. According to EDM data, only 23% of participants at 3 months and 15% at 6 months took 95% or more of their prescribed medication over the previous 4 weeks (over the previous 3 months, levels dropped to 15% and 10%). Of course, when the EDM is not opened we cannot determine whether the participant missed a dose of medication or simply was not using the device (Bova et al., 2005). A multiple regression analysis of self-reported 3-day baseline adherence revealed no significant differences by sex, age, race/ethnicity, sexual orientation, education, income, employment, or relationship status. Overall, this set of sociodemographic indicators accounted for only 7% of the variance in adherence.

Evaluation of Intervention Effects

A priori intent-to-treat analyses—The primary tests of intervention effect examined group differences in medical record-extracted HIV–1 RNA viral load at 3 and 6 months. Analyses of secondary outcomes consisted of tests of group differences at both the 3- and 6-month assessments in (a) self-reported 3-day adherence, (b) EDM 4-week and 3-month adherence, (c) satisfaction with social support, and (d) depressive symptomatology. For every comparison, two-tailed *t* tests were used in intent-to-treat analyses involving all participants who were randomly assigned and for whom we had outcome data at the relevant

assessment point. Results from these *t* tests indicate no differences by condition for any of the primary or secondary outcomes except for social support, which, as mentioned previously, was different at baseline (see Table 2).

Post hoc as-treated analyses—One possible explanation for the null findings is the low level of participation in the peer intervention. Descriptive data indicated that 23% of the participants randomly assigned to the peer support intervention attended no peer meetings, and only 17% attended five or six meetings; participants attended an average of 2.1 meetings (*SD* = 1.9; range = 0 to 6). The average number of telephone contacts for intervention participants was 5.8 (*SD* = 4.5; range = 0 to 17). The nonsignificant intervention effects may have resulted from this low level of exposure to the intervention rather than its lack of efficacy. To investigate this hypothesis, we conducted two sets of post hoc analyses.

First, in post hoc as-treated analyses, peer support intervention participants who attended at least two group meetings ("intervention completers"; $n = 36$ of the original 71 randomized to this condition) were compared with SOC participants. The use of this standard resulted in a median split of the peer support intervention participants, as 51% in the peer intervention condition attended two or more group meetings. Compared with other participants randomized to the peer support intervention, the intervention completers were similar in terms of sociodemographic factors and self-reported adherence at baseline with one exception: They were less likely to report lifetime heavy use of crack or heroin (70% vs. 42%, respectively), $\chi^2(1, N = 136) = 5.50$, $p < .05$. Results of these analyses using two-tailed *t* tests revealed no significant intervention effects between intervention completers and SOC participants on any of the primary or secondary outcomes (see Table 2).

The second set of post hoc analyses focused solely on the 71 participants randomized to the peer support intervention. Multiple regression analyses controlling for baseline self-reported 3-day adherence were used to examine the association between the number of group meetings attended (a rough estimation of the "dose" of the intervention received) and the primary and secondary outcomes. Results indicated that intervention participation, although not associated with EDM adherence or HIV–1 RNA viral load at either assessment, was positively associated with social support at 3 months ($\beta = 0.29$, $p < .05$), as well as 3-day self-reported adherence ($\beta = 0.30$, $p < .05$), social support ($\beta = 0.35$, $p < .05$), and depressive symptomatology ($\beta = -0.27$, $p < .05$) at 6 months.

Discussion

In an effort to address the widespread problem of nonadherence to antiretroviral medication, we developed and evaluated a peer support intervention. Findings from a priori intent-to-treat analyses, as well as post hoc as-treated analyses of intervention completers, indicated no significant differences in medical record-extracted HIV–1 RNA viral load (the primary outcome) or adherence according to self-reported and EDM, social support, and depressive symptomatology at 3 and 6 months (the secondary outcomes).

However, further post hoc analyses among all participants in the peer support intervention group revealed a significant association between amount of exposure to the intervention

(i.e., number of group meetings attended) and social support at 3 months as well as self-reported adherence, social support, and depressive symptomatology at 6 months, even after controlling for baseline adherence.

The lack of intervention effects in the between-conditions comparisons is disappointing but not entirely surprising given the limited and inconsistent literature on efficacious HAART adherence interventions. Nonadherence to HAART has proven to be an intractable problem, with long-lasting changes especially elusive.

Given the dearth of research on adherence interventions in general, and peer-support interventions in particular, it is difficult to contextualize our results. Although the trial was moderately underpowered, the size of the difference in the outcomes between conditions suggests that power was not an issue. Instead, the lack of intervention effects may be due to factors related to the intervention trial itself or to characteristics of the sample. These potential explanations are elucidated below, along with other limitations of the study and implications for future research.

Two factors related to the intervention trial may have contributed to the null findings. First, the 3-month intervention may have been excessively brief. Peer intervention participants may have been slow to develop the trust necessary to share their personal thoughts and feelings with an assigned peer, limiting the creation of socially supportive relationships that were predicted to arise and improve adherence. Second, participants in the peer support intervention may not have received sufficient exposure to the intervention to impact social support or depressive symptomatology, the purported mechanisms for change in adherence. That is, a 3-month intervention may be sufficient in length, but only if participants are fully engaged for the entire duration. Recall that only 17% of intervention participants attended five or six meetings and that participants averaged only 5.4 telephone contacts with a peer during the 3-month intervention. Our finding of a significant positive association between number of peer meetings attended and several outcomes provides some support for the supposition that limited exposure to the intervention contributed to the null findings.

Why was exposure to the intervention so low? Although we did not systematically assess reasons for group nonattendance, it is possible that the lack of compensation for attendance at the group meetings diminished motivation to attend. Other potential factors hampering attendance include scheduling conflicts, difficulty traveling to the clinic, lack of child care, insufficient connection to the assigned peer, or concerns about lapses in confidentiality. More than one participant clearly stated to research staff that they would avoid the group meetings for fear of encountering someone they know who could then disclose their HIV-positive status to mutual acquaintances. With respect to the telephone component of the intervention, peers sometimes reported participants lacked reliable telephone numbers (e.g., some had access only to a lobby pay phone in a group home), kept irregular hours, or failed to return calls.

There are two related concerns that warrant attention because of their potential impact on future trials, even though data from the current sample cannot address them. First, perhaps even full exposure to an even longer intervention would not have increased social support

and decreased depressive symptomatology. Reaping the benefits of social connectedness might require more than occasional contact with an assigned stranger, even one with a minimal shared experience. It may require daily human contact from a significant other or another more readily available support, such as that offered by AIDS service organization drop-in centers. Similarly, ameliorating depressive symptomatology, especially at higher levels, may require professional intervention in the form of psychotherapy or pharmacotherapy and not merely the support of an empathic peer. Second, even if the intervention (in whatever dose) could increase social support and decrease depressive symptomatology, these benefits might not directly impact adherence behavior or clinical outcomes. Consistently optimal adherence involves a complex array of behaviors with multiple determinants (Ammassari et al., 2003). Although insufficient social support and depressive symptomatology are consistent correlates of nonadherence, addressing them may not be sufficient to improve adherence in the face of multiple competing barriers.

Beside issues related to the intervention trial, characteristics of the sample may have diminished intervention effects in the current study. First, participants may have had more pressing problems than HIV medication adherence, such as struggles to obtain stable housing and sufficient food for themselves and their families. Interventions that ignore these more basic needs in low-resource populations may not be able to achieve success with more peripheral goals such as medication adherence (Moss et al., 2004).

In addition, high levels of current substance use in our sample may have limited the ability of participants to benefit from the intervention. Active substance use per se has not been shown to consistently predict lower levels of adherence (Ammassari et al., 2003). However, the chaotic lifestyle resulting from past and present substance use that interferes with an ability to meet basic needs has been documented as a significant barrier to HAART adherence (Celentano et al., 1998). Recall that in the current sample, lifetime heavy alcohol and other substance use was highly prevalent and more common among those who failed to complete the intervention.

Third, our eligibility criteria were very inclusive, which led to a heterogeneous sample in terms of baseline values on our main outcome variables. Participants satisfied with their current social support, lacking any depressive symptomatology, and maintaining high levels of adherence with concomitantly low HIV–1 RNA levels might lack motivation to adhere to the intervention and therefore might be less likely to experience intervention effects.

Finally, our sample was an experienced HIV population. At baseline, participants had known their HIV-positive status for an average of more than 8 years, had been on HAART for more than 2 years, and had been on more than three previous regimens. Even full exposure to a powerful adherence intervention may not have been enough to overcome these participants' history of chronic nonadherence. Perhaps a longer, more intensive, multimodal intervention would be better suited for such a HAART-experienced group. Similarly, resistance to multiple antiretroviral medications as a result of inconsistent adherence in our sample may have decreased participants' ability to achieve viral suppression, no matter how efficacious the intervention or how consistent their adherence. As an individual is most likely to experience viral suppression on the first HAART regimen, perhaps interventions

should target individuals at HAART initiation, early in treatment, or even beforehand using pretherapy preparedness training.

This discussion of our participants' characteristics underscores the limited generalizability of our results. Although our sample represents an increasingly prevalent subgroup of individuals with HIV/AIDS, our participants differ significantly from other segments of the HIV-positive population who may be more amenable to a peer support intervention. Replication with different samples is required to address this issue.

Future research should capitalize on the lessons learned from this trial and avoid its limitations. Long-term, multifactored interventions (i.e., aimed not only at enhancing social support) should be developed and tested empirically in larger RCTs. Such studies would also benefit from targeting and prescreening potential participants for suitability on the basis of the nature of the intervention. For example, patients with low social support and high depressive symptomatology or who show signs of poor adherence may be more willing to participate in a peer support intervention such as the one we tested, more highly motivated to comply, and more likely to benefit. It remains unclear what length or type of intervention will yield the most benefit. However, a recent review of HIV adherence RCTs was encouraging with respect to a range of strategies, including even brief individualized counseling and education, reminder aids in the form of pager text messages, and cue-dosing with monetary reinforcement at least for the short term (Simoni et al., 2006). Whatever their strategy, future HAART adherence intervention trials must be adequately powered, prioritize retention, and include sufficiently intense interventions and timely follow-ups. Any salient needs of the targeted population should be addressed by the intervention (e.g., lack of stable housing or highly prevalent active substance use). Finally, investigators should be sure to publish and discuss null findings to deter further work in less promising areas.

An expansion of the present study is underway. The new trial involves a 2 × 2 factorial design, comparing a similar peer support intervention with a two-way text paging system. The same intervention dose is planned (3 months), but follow-up has been doubled (with assessment points 3 and 6 months postintervention). Also, the target sample size is larger (N = 240) and eligibility is restricted to HAART-naive individuals or those switching to a new regimen of combination therapy. Finally, to increase attendance, participants are compensated $15 for each group meeting they attend. These modifications may improve the effectiveness of a clinic-based peer support intervention and otherwise help to confront the seemingly intractable problem of HAART nonadherence.

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Table 1

Sample Characteristics of Participants at Baseline

	Total (*N* = 136)		Standard of care (*n* = 65)		Peer intervention (*n* = 71)	
Variable	***n***	**%**	***n***	**%**	***n***	**%**
Gender						
Male	75	55.1	40	61.8	35	49.3
Female	61	44.9	25	38.5	36	50.7
Race/ethnicity						
African American	63	46.3	28	43.1	35	49.3
Hispanic	60	44.1	31	47.7	29	40.8
Caucasian	9	6.6	3	4.6	6	8.5
Other	4	2.9	3	4.6	1	1.4
Education						
High school degree/GED	76	56.3	36	56.3	40	56.3
Less than high school	59	43.7	28	43.8	31	43.7
Employment status						
Employed	20	14.7	7	10.8	13	18.3
Unemployed	116	85.3	58	89.2	58	81.7
Monthly income						
Less than $500	40	30.8	24	40.0	16	22.9
$501–$1,000	70	53.8	32	53.3	38	54.3
Greater than $1,000	20	15.4	4	6.7	16	22.9
Lifetime heavy substance use[a]						
Alcohol (to drunkenness)	70	51.5	31	47.7	34	47.9
Crack or heroin	68	50.0	35	53.8	35	49.3
HAART experience						
Naive (<3 months)	14	20.4	10	15.6	4	5.6
Up to 2 years	35	25.9	18	28.1	17	23.9
More than 2 years	86	63.7	36	55.4	50	70.4
CD4 at baseline						
0–200 cells	54	40.3	25	39.1	29	41.4
201–400 cells	47	35.1	25	39.1	22	31.4
More than 400 cells	33	24.6	14	21.9	19	27.1
	M	*SD*	*M*	*SD*	*M*	*SD*
Age (in years)	42.6	8.9	42.5	9.1	42.6	8.8
Years since HIV diagnosis	7.8	4.6	7.5	5.1	8.0	4.2
No. of previous regimens	3.2	3.2	3.2	4.0	3.3	2.2

Note. GED = graduate equivalency degree; HAART = highly active antiretroviral therapy.

[a]Used at least 3 times per week for at least 1 month.

Table 2

Data on Primary and Secondary Outcomes of Peer Support Intervention by Condition at All Assessment Points

	Peer support intervention condition			Standard of care condition		
Assessment	***n***	***M***	***SD***	***n***	***M***	***SD***
Social support[a]						
Baseline	71	3.0	0.7	65	3.3	0.7
3 months	54	3.1	0.7	51	3.2	0.6
6 months	59	3.0	0.8	57	3.3	0.7
Depressive symptomatology						
Baseline	71	19.9	12.4	65	19.6	11.2
3 months	54	17.6	11.6	51	16.4	11.5
6 months	59	21.3	14.5	57	17.9	11.2
Adherence (%)						
Self-report (3-day)						
Baseline	71	80.3	31.1	64	75.7	36.4
3 months	51	79.9	33.2	50	79.9	35.9
6 months	59	68.2	44.2	53	76.3	37.3
EDM (4-week)						
3 months	42	54.0	39.0	45	56.9	34.8
6 months	45	42.1	39.5	49	45.4	37.8
EDM (3-month)						
3 months	45	53.9	35.2	53	58.9	31.0
6 months	42	37.7	36.0	49	48.1	36.3
HIV-1 RNA viral load (ln transformed)						
Baseline	62	8.0	3.0	60	8.4	3.2
3 months	63	7.5	3.0	60	6.7	3.1
6 months	62	7.4	3.0	56	6.9	3.0

Note. All participants with nonmissing data at the designated time points were included in the analyses. EDM = electronic drug monitor; ln = natural logarithm.

[a]Differences between standard of care and intent-to-treat conditions were significant at baseline ($t = 2.06$, $p < .05$) and remained so at 6 months ($t = 2.11$, $p < .05$). No other between-conditions findings were significantly different.