Published in final edited form as:
AIDS Educ Prev. 2012 February ; 24(1): 1–14. doi:10.1521/aeap.2012.24.1.1.

Community HIV Treatment Advocacy Programs May Support Treatment Adherence

Laura M. Bogart, PhD,
Children's Hospital Boston & Harvard Medical School

Glenn J. Wagner, PhD,
RAND Corporation

Matt G. Mutchler, PhD,
California State University, Dominguez Hills & AIDS Project Los Angeles

Brian Risley, MFA,
AIDS Project Los Angeles

Bryce W. McDavitt, BA,
California State University, Dominguez Hills & AIDS Project Los Angeles

Tara McKay, MA, and
University of California, Los Angeles & AIDS Project Los Angeles

David J. Klein, MS
Children's Hospital Boston & Harvard Medical School

Abstract

Treatment advocacy (TA) programs, based in AIDS service organizations and clinics, aim to engage clients into care and support antiretroviral treatment (ART) adherence through client-centered counseling; advocate for patients with providers; and provide social service referrals. Systematic evaluations of TA are lacking. We conducted a non-randomized evaluation examining relationships of TA participation to adherence, care engagement, social services utilization, unmet needs, patient self-advocacy, and adherence self-efficacy among 121 HIV-positive clients (36 in TA, 85 not in TA; 87% male, 34% African American, 31% White, 19% Latino). In multivariate models, TA participants (vs. non-TA participants) showed higher electronically monitored [85.3% vs. 70.7% of doses taken; b(SE)=13.16(5.55), p<.05] and self-reported [91.1% vs. 75.0%; b(SE)=11.60(5.65), p<.05] adherence; utilized more social service programs [Ms = 5.2 vs. 3.4; b(SE)=1.97(0.48), p<.0001]; and had fewer unmet social-service needs [Ms = 1.8 vs. 2.7; b(SE)= −1.06(0.48), p<.05]. Findings suggest the need for a randomized controlled trial of TA.

INTRODUCTION

Early and ongoing engagement in care is critical for people living with HIV (PLWH) to benefit from life-prolonging HIV treatment and to remain free from opportunistic infections. Nevertheless, a significant proportion of PLWH delay entry into HIV medical care after diagnosis until the disease has progressed or do not seek routine care (Gardner et al. 2005; Teshale et al. 2005; Gardner, McLees, Steiner, Del Rio, & Burman 2011). For example, one study found that 40% of newly diagnosed individuals had not initiated HIV medical care

---

Address correspondence and requests for reprints to Laura M. Bogart, PhD, laura.bogart@childrens.harvard.edu, Division of General Pediatrics, Children's Hospital Boston, 300 Longwood Avenue, Boston, MA 02115; Phone: 857-218-4073; Fax: 617-730-0957.

within 6 months of diagnosis (Gardner et al. 2005). Even with more potent ART regimens, relatively high levels of adherence (i.e., 75–90% of prescribed doses) (Bangsberg 2006; Shuter, Sarlo, Kanmaz, Rode, & Zingman 2007) are still needed for viral suppression (Paterson et al. 2000; Mugavero et al. 2007) in order to gain optimal benefit from treatment and decrease risk of mortality (Giordano et al. 2003; Bangsberg et al. 2006; Gardner et al. 2009). However, studies generally show adherence below these levels; for example, a meta-analysis indicated that only 62% of participants across 84 studies showed adherence levels of 90% of doses prescribed (Ortego et al. 2011), and a survey of people in care for HIV in the US found that 35% reported missing at least one dose in the past month (Blair et al. 2011).

A variety of social services, funded mostly through the Ryan White CARE Act, facilitate access to care for PLWH (e.g., case management, drug reimbursement, mental health treatment). Receipt of such services is related to primary care entry, use of ART (Katz et al. 2001), treatment retention (Magnus et al. 2001; Ashman, Conviser, & Pounds 2002; Chan, Absher, & Sabatier 2002; Conviser, & Pounds 2002; Lo, MacGovern, & Bradford 2002; Messeri, Abramson, Aidala, Lee, & Lee 2002; Sherer et al. 2002; Soto, Bell, Pillen, & HIV/AIDS Treatment Adherence Health Outcomes and Cost Study Group 2004; Gardner et al. 2005), HIV health literacy, and positive perceptions of medical providers (Katz et al. 2001; Magnus et al. 2001; Ashman et al. 2002; Chan et al. 2002; Conviser, & Pounds 2002; Lo et al. 2002; Messeri et al. 2002; Sherer et al. 2002; Soto et al. 2004; Gardner et al. 2005; Van Servellen et al. 2005). One program in particular, treatment advocacy (TA), has been sustained by AIDS service organizations (ASOs) across the U.S. for much of the HIV epidemic, demonstrating the feasibility of such programs for use in the community. TA facilitates clients' navigation through the medical system and provides HIV disease and treatment education through one-on-one sessions and community education forums, as well as referrals to services for subsistence and health needs (e.g., mental health, substance use, housing, food/nutrition programs). Community-based programs such as TA may be critical for engaging and supporting individuals who are reluctant to attend programs within a medical setting due to, for example, mistrust of healthcare or treatments (Mutchler et al. 2011). However, the effects of TA on client adherence and engagement in care have not been systematically evaluated.

We conducted a qualitative process evaluation of TA at a large ASO in Los Angeles County, in which we conducted interviews with 25 TA clients, 2 treatment advocates, and 4 HIV providers who managed the care of patients in the TA program (Mutchler et al. 2011). Five interconnected themes consistently emerged across clients, treatment advocates, and providers. Treatment advocates helped clients *understand treatments* and supported adherence *within a holistic context* that included referrals to needed social services. TA acted as a *bridge to providers* and helped clients build *self-advocacy skills*. Further, providers, treatment advocates, and clients viewed *TA as a way to lower levels of medical mistrust* regarding treatments and medical providers, by providing a safe place to discuss HIV and other health issues outside of the medical setting.

In the present study, we complemented our qualitative process evaluation with a quantitative study of the same TA program. We compared a sample of clients currently receiving TA services to a sample of clients at the same ASO who were not receiving TA services. We hypothesized that TA clients would exhibit higher levels of treatment adherence, greater engagement in care, more utilization of social services, fewer unmet social services needs, stronger patient self-advocacy beliefs, and greater self-efficacy to adhere to treatment. In addition, because clients were not randomized into TA (i.e., they self-selected into the program), we compared TA and non-TA clients on socio-demographic and healthcare characteristics, in order to test whether a selection bias existed among clients who did, versus did not, participate in the TA program.

METHODS

Study setting

This study was conducted at AIDS Project Los Angeles (APLA), the largest ASO in Los Angeles County and the second largest ASO in the U.S., with the mission of improving the lives of PLWH, reducing HIV incidence, and advocating for fair and effective HIV-related public policy. APLA provides services (e.g., case management, career counseling, job placement, substance use, mental health, food and nutrition, housing, transportation, treatment advocacy) to more than 7,500 adults and children with HIV annually. The overall clientele of APLA is approximately 37% Latino, 36% White, and 24% African American (3% are of other races/ethnicities); roughly 10% of clients are female. Client racial/ethnic and gender distribution is similar to those for people with AIDS in Los Angeles County (HIV Epidemiology Program 2010).

We used community-based participatory research (CBPR), in which community stakeholders (i.e., research and program staff and clients at APLA) and academic researchers contributed jointly to every phase of the project (Viswanathan et al. 2004; Israel, Eng, Schulz, & Parker 2005; Bogart, & Uyeda 2009). The impetus for the study originated in discussions with APLA staff, who approached the academic researchers to partner on a TA program evaluation. APLA's ongoing TA community advisory board – composed of APLA clients in TA, treatment advocates, and a medical provider – provided a forum for idea exchange and community input throughout the project. APLA's and RAND's human subjects review boards approved the study.

APLA's Treatment Advocacy Program

Counselor training—Treatment advocates have bachelor's degrees in health-related sciences and complete a three-day training to certify in treatment education. They are required to demonstrate extensive knowledge in HIV transmission, testing, pathogenesis, the human immune system, disease states and HIV treatment options. They are also required to receive 20 hours per year of ongoing HIV education through national and local conferences and trainings.

TA components—Treatment advocates use tailored client-centered counseling and motivational interviewing to assess clients' treatment needs, health issues, healthcare access, disease indicators, medication status, adherence (if applicable), substance use, depression, and HIV knowledge; intervene with physicians to improve patient-provider relationships and recommend changes to treatment regimens (if necessary); and provide necessary referrals to social services (e.g., substance use, mental health, housing, nutrition, transportation). Treatment advocates and clients jointly develop an Individual Service Plan (ISP) to set short- and long-term goals, identify barriers to engagement in care and adherence, and identify concrete tasks for both the treatment advocate (e.g., interfacing with physician) and client (e.g., following up on referrals to housing assistance) to undertake toward overcoming barriers. The amount of time clients spend in TA varies between one individual session and ongoing intermittent sessions, depending on clients' needs.

Participant recruitment and screening

TA clients were recruited for the study via fliers distributed by treatment advocates to clients during their usual appointments, or left at key locations at the ASO; and face-to-face interactions with clients coming to the ASO for specific programs and services (e.g., case management, transportation assistance, food bank). Non-TA clients were recruited by fliers left at key locations in the ASO or given to clients of specific programs and services. Different flier versions were created to target TA clients and non-TA clients, including those not regularly engaged in care and those who were currently on ART.

The fliers invited potential participants to telephone for eligibility screening. Eligibility criteria included: being (1) HIV-positive, (2) 18 years of age or older, (3) a registered APLA client, and (4) either on ART, or not on ART with a CD4 count <350 (i.e., the level at which ART was recommended by guidelines at the time of the study). Clients not on ART who had CD4 counts ≥350 were ineligible, because TA counseling about treatment was less relevant to their immediate condition. Clients were also ineligible if they had been offered TA in the last 6 months and refused (because such an action would introduce selection bias into the non-TA group). To ensure variability and maximize statistical power, we used a screening tool to purposively recruit sufficient numbers of TA and non-TA clients who were on ART and not on ART (with CD4 counts <350), as well as clients not adequately engaged in care (i.e., no medical visit in the last 3 months).

We recruited 121 participants (36 TA clients and 85 non-TA APLA clients) from July 2008 to March 2009. At the time of the study, the TA program was funded through the Los Angeles County Department of Public Health to deliver services to a minimum of 57 clients, of whom 46 were approached for enrollment. Of the 46, 42 were found to be eligible, and 36 enrolled (86%). (Four were not eligible because they were not on ART due to having CD4 counts >350.) Six TA clients who were contacted did not participate (one declined due to lack of time, and five did not show up to their appointment after multiple attempts at scheduling). Of the 36 TA clients enrolled, two were not engaged in care and not on ART, one was not engaged and on ART, six were engaged and not on ART, and 27 were engaged and on ART. Of the 85 non-TA clients, 12 were not engaged in care and not on ART, nine were not engaged and on ART, 29 were engaged and not on ART, and 35 were engaged and on ART. Sample sizes differed between the TA and non-TA groups because we were more easily able to enroll non-TA clients, who were drawn from APLA's large client base, versus TA clients, for which there was a smaller pool of potential participants during the study period.

Longitudinal assessments

Participants completed 1-hour interviews at baseline, and at 3- and 6-month follow-up. Participants were paid $25 for each assessment. To facilitate tracking and decrease the likelihood of loss to follow-up, participants were asked to check in by phone, email, or in person 5 times over the course of the study (in between the assessments: three times before the 3-month follow-up, and twice before the 6-month follow-up) to update their contact information and confirm the next interview appointment. Participants received $5 for each check-in. Participants who completed all interviews and check-ins received $100 total.

Of the 121 clients who completed interviews at baseline, 107 (88%) returned at 3-month follow-up, and 106 (88%) returned at 6-month follow-up; 104 (86%) completed all 3 surveys. These percentages were similar for TA and non-TA participants: In the TA client group (n=36), 92% returned at 3 months, 92% returned at 6 months, and 89% returned for both. In the non-TA client group (n=85), 87% returned at 3 months, 86% returned at 6 months, and 85% returned for both.

Participants who dropped out of the study after baseline were compared to those who were retained for the 6-month assessment on socio-demographic characteristics (i.e., age, race/ethnicity, sexual orientation, employment status, housing status), education, medical characteristics (i.e., length of time since diagnosis, AIDS diagnosis, CD4 count, viral load, AIDS symptom severity), and the main study outcome (i.e., self-reported and electronically monitored adherence, engagement in care). Participants who completed the 6-month assessment differed from the 15 participants who dropped out of the study after the baseline or 3-month follow-up survey on housing status, dichotomized as stably housed (i.e., rented or owned home/apartment; in residential treatment facility; in subsidized housing) versus not stably housed (i.e., in friend/relative's home/apartment, temporary/transitional housing, or homeless). Specifically, 96% of participants who were stably housed completed the 6-month assessment versus 72% who were not stably housed (Fisher's Exact test $p = .0003$). This difference in housing status was significant within the TA and non-TA groups as well (both Fisher's Exact test p-values $< .05$).

Primary outcomes of TA

Adherence—Adherence was monitored electronically for six months post-baseline using the Medication Event Monitoring System (AARDEX Inc 2005), which consists of bottle caps that record times when medication bottles are opened. Electronic monitoring software yields detailed reports of daily medication-taking patterns and calculates the percentage of total scheduled doses actually taken in a format suitable for conversion to a statistical analysis package. Adherence was monitored for the medication with the most complex regimen only (Arnsten et al. 2002). At each follow-up, MEMS data were downloaded and participants answered questions assessing whether and how often they opened the bottle without removing a dose, took a dose from a source other than the MEMS bottle, and removed multiple doses at a time over the past two weeks. These responses were used to adjust electronic scores for a more valid assessment of adherence in the past two weeks at both 3 months and 6 months post-baseline (Bangsberg et al. 2000). For our primary outcome measure, we examined average adherence in the past two weeks across data from both the 3-month and 6-month assessments, available for 55 (82%) of the 67 participants on ART. At each time point, participants on ART reported the percentage of doses taken in the past month on a single-item visual analog scale (Walsh, Mandalia, & Gazzard 2002; Simoni et al. 2006). We calculated the average percentage of doses taken across all three assessments.

Engagement in care—Engagement in care was derived from two variables at baseline: "In the past three months, how many scheduled appointments did you have with your HIV provider/doctor?" and "How many of these did you miss?" Participants were defined as not engaged in care if they did not have any healthcare visits, or if they reported at least 2 missed visits, in the past three months. Participants who reported attending at least one medical visit and who did not report any missed visits in the past three months were considered to be engaged in care (Rumptz et al. 2007).

Secondary outcomes of TA

We measured proximal, immediate factors that could change as a result of TA participation, due to TA's primary activities regarding provision of referrals for social services (e.g., housing for PLWH) and mental health counseling, strengthening of clients' self-advocacy skills, and provision of treatment education tailored to clients' specific barriers. Thus, we examined whether clients in TA had *lower unmet need for social services* and *more involvement in HIV-related social services programs,* and were more likely to be *stably housed versus homeless or in transitional/temporary housing*; we also examined whether clients in TA had *higher self-advocacy beliefs* and *greater self-efficacy to adhere*.

Unmet non-medical needs were examined using a measure adapted from the HIV Cost and Services Utilization Study (Cunningham et al. 1999). Participants were given a list of 14 services (e.g., counseling/mental health treatment, substance abuse treatment, housing) and asked if they needed the service in the last 6 months, and if so, whether the problem had been resolved. Those who reported that the problem had not been resolved were considered to have an unmet need; the number of unmet needs was summed. In addition, participants were given a list of 18 services provided by APLA (e.g., case management, mental health services, crystal methamphetamine program), with an extra write-in space for “other” services used, and asked to check all services used in the past year. Responses were summed for a measure of number of services used. We assessed current housing status using a checklist of different housing situations; responses were coded as stable (response options: rent or own home/apartment, subsidized housing) or unstable (response options: friend/relative’s home/apartment, residential treatment facility, temporary/transitional housing, homeless).

Patient self-advocacy was measured with a 12-item scale developed in prior research (Brashers, Haas, & Neidig 1999). A sample item is, “If my doctor prescribes something I don’t understand or agree with, I question it” with response items 1, strongly disagree to 5, strongly agree. Internal reliability was high ($\alpha = .73$). We used a one-item measure of adherence self-efficacy: On a scale from 0 to 10, participants indicated how confident they were that they could follow their ART dosing instructions exactly as prescribed, with labels 0, Cannot do at all; 5, Moderately certain I can do; and 10, Certain I can do (Chesney et al. 2000).

Potential covariates and confounding variables (that could contribute to self-selection into TA)

Socio-demographic characteristics—Participants were asked their gender, age, race/ethnicity (with response options American Indian or Alaska Native, Asian, Black/African American, Latino/Hispanic, Native Hawaiian or other Pacific Islander, White, or Other; participants could endorse more than one race/ethnicity); sexual orientation (with response options straight/heterosexual, gay/homosexual, lesbian/homosexual, same gender loving, bisexual, and other); education (1st to 6th grade, 7th to 11th grade, high school degree or GED, some college but no degree, college degree, some graduate but no degree, graduate degree); and current annual income (none, <$10,000, $10,001–$20,000; $20,001–$30,000; $30,001–$40,000, >$40,000). Sexual orientation was dichotomized into heterosexual versus the other response options; race/ethnicity was recoded into two variables: Black versus other categories, and Latino versus other categories; and annual income was dichotomized into < $10,000 versus ≥$10,000 annually. Education was dichotomized into high school degree or less versus at least some college.

Medical factors—Length of time since HIV diagnosis (in months) was measured by asking participants the month and year when they first tested positive, and subtracting it from the interview month and year. Participants gave consent for extracting CD4 count and viral load from their medical records. Of the 121 participants, we obtained CD4 count for 91 and HIV viral load for 88. CD4 counts were dichotomized as <200 versus ≥200. HIV viral load was coded as detectable versus undetectable (<50 copies). Because self-reported and medical records dichotomous CD4 count were highly correlated ($r=.76$, $n=75$, $p < .0001$), and self-reported and medical records dichotomous viral load were moderately correlated ($r=.47$, $n=71$, $p<.0001$), we substituted self-reported CD4 and/or viral load values for the 31 participants missing CD4 count and/or viral load. Supporting the validity of this approach, prior research suggests that self-reported CD4 values are highly associated with medical records data among PLWH (Cunningham, Rana, Shapiro, & Hays 1997).

Statistical analysis

Association of TA with primary outcomes—We tested whether TA clients exhibited greater adherence to ART and engagement in care than did non-TA clients. Bivariate linear regression models were conducted to compare TA and non-TA clients on electronically monitored adherence using the average of adherence at the 3-month and 6-month time-points, on self-reported adherence averaged across the baseline, 3-month, and 6-month responses, and on engagement in care at baseline. Multivariate models were then conducted that controlled for socio-demographic and medical variables that were related to TA group membership or the adherence or engagement in care outcomes at an alpha level of $p< .10$, to rule out any potentially confounding variables of the relationship of TA with adherence and/or engagement in care. Because we did not randomize individuals to receive or not receive TA, controlling for these factors allowed us to understand whether certain types of individual characteristics are more likely to be associated with participation in TA, and thus whether any effects of TA might be due to a selection bias rather than actual effects of the program on the outcomes. The following potential covariates were tested, using an alpha-level of $p< .10$: gender (male), age, Black race, Latino ethnicity, low income, low education, heterosexual orientation, time since HIV diagnosis, low CD4, and undetectable viral load. All TA clients were included in the analysis, regardless of the extent to which they utilized TA.

Association of TA with secondary outcomes—We used bivariate and multivariate models to test proximal factors that TA could directly affect through counseling and referrals: use of social services (i.e., involvement in other ASO programs), unmet needs for social services, stable housing status, patient self-advocacy and self-efficacy for medication adherence. Multivariate models controlled for socio-demographic and medical characteristics associated with either TA or the secondary outcomes at an alpha-level of $p< .10$.

RESULTS

Participant characteristics

Table 1 shows participant characteristics of the overall sample, and for the TA and non-TA client groups separately. Of the 121 participants at baseline, most (87%) were male (average age=43.2±8.3), and most were gay or bisexual (75%). A large proportion (68%) had incomes below $10,000 annually, 41% had a high school degree or less, and 64% were in stable housing (versus 36% in temporary/transitional housing or homeless). A total of 40% were African American, 34% were White, and 24% were Latino. Compared to the APLA client base, we recruited a disproportionately greater percentage of African Americans, and a disproportionately lower percentage of Latinos, possibly because we did not have resources to enroll Spanish-speaking clients in the study. TA and non-TA client groups only significantly differed on education, such that a smaller percentage of participants in the TA group (25%) versus the non-TA group (48%) had a high school degree or lower level of education, $p < .05$.

Bivariate and multivariate relationships of TA to treatment adherence

Past two-week electronically monitored adherence (averaged across the 3- and 6-month follow-up assessments) was greater among TA ($M = 85.3$, $SD = 16.6$, $n = 22$) than non-TA participants ($M = 70.7$, $SD = 19.2$, $n = 26$; b (SE) = 15.0 (5.3), $p < .01$). Self-reported adherence in the past month (averaged across the 3- and 6-month survey responses) was greater among TA ($M = 91.1$, $SD = 7.7$, $n = 31$) than non-TA participants [$M = 75.0$, $SD = 28.2$, $n = 56$; b (SE) = 16.1 (5.2, $p < .01$). A higher percentage of TA participants (92%) versus non-TA participants (75%) were engaged in care at baseline, odds ratio (OR) = 3.61, 95% confidence interval (CI) = 1.003, 12.98, $p < .05$.

Of the potential covariates for the multivariate analysis, length of time since diagnosis, viral load, and education were significantly associated with TA participation: participants in TA had been diagnosed for a shorter period of time (M = 99.7 months, SD = 81.1) than participants not in TA (M = 144.5 months, SD = 77.9), $p < .01$; a greater percentage of participants in TA (79%) had undetectable viral loads than participants not in TA (54%), $p < .05$; and as noted above, a lower percentage of TA participants had a high school degree or less, $p < .05$. Several participant characteristics were also associated with adherence at $p < .05$ or $p < .10$: Black race was significantly related to lower electronically monitored adherence [b (SE) = −14.3 (5.3), $p < .01$], and Latino ethnicity was marginally associated with lower electronically monitored adherence [b (SE) = 12.8 (6.5), $p < .06$]. CD4 counts of <200 were associated with lower electronically monitored adherence [b (SE) = −18.6 (8.7), $p < .05$]. Having a low CD4 count [b (SE) = −13.9 (6.5), $p < .05$] and a detectable viral load were related to lower self-reported adherence [b (SE) = −20.6 (5.8), $p < .001$]. Having a detectable viral load was also marginally associated with not being engaged in care [OR = 2.48 (95% CI = 0.98, 6.27), $p < .06$]. Thus, all multivariate models controlled for length of time since diagnosis, low education, and viral load, which were related to TA status ($p < .05$); models for electronically monitored adherence additionally controlled for Black race, Latino ethnicity, and CD4 count; and models for self-reported adherence additionally controlled for CD4 count.

As shown in Table 2, multivariate results indicated that the association of TA to electronically monitored adherence [b (SE) = 14.3 (5.5), $p < .05$; n for TA clients = 22, n for non-TA clients = 32] and self-reported adherence [b (SE) = 13.1 (5.6), $p < .05$; n for TA clients = 29, n for non-TA clients = 52] remained significant in multivariate models controlling for potentially confounding variables of the effects of TA (i.e., covariates related to TA and/or the outcome). Of the covariates, having a lower CD4 count [b = −20.02 (8.68), $p <.05$] and being Black [b = −13.55 (6.04), $p <.05$] were associated with lower electronically monitored adherence, and having a detectable viral load was associated with lower self-reported adherence [b = 17.32 (6.60), $p <.05$]. The association of TA to engagement in care was not significant in multivariate models [OR = 2.64 (95% CI = 0.67, 10.36), n for TA clients = 34, n for non-TA clients = 81].

Examination of secondary outcomes of TA

We examined whether TA was related to secondary outcomes directly relevant to TA's in-session activities, including number of ASO services used in past year, number of unmet service needs, stable housing status, patient self-advocacy, and adherence self-efficacy. TA clients used a greater percentage of services at the ASO than did non-TA clients (Ms = 5.2±2.6 vs. 3.4±2.0, respectively), [b (SE) = 1.8 (0.4), $p < .0001$]; and had fewer unmet needs for social (non-medical) services (Ms = 1.8±2.1 vs. 2.7±2.4, respectively), [b (SE) = −0.9 (0.5), $p < .05$]. TA was not significantly associated with stable housing status (OR = 2.04, 95% CI = 0.85 – 4.88, $p = .11$), patient self-advocacy [b (SE) = −0.1 (0.1), $p = .35$], or adherence self-efficacy [b (SE) = 0.5 (0.4), $p = .22$]; thus, these variables were not examined further in multivariate models.

All multivariate models for secondary outcomes controlled for length of time since diagnosis, undetectable viral load, and low education, all of which were significantly associated with TA status, as previously noted. For unmet needs, we additionally controlled for age and low income: younger individuals [b = −0.1 (0.02), $p < .01$] and those of lower income [b = 1.0 (0.5), $p < .05$] had a greater number of unmet social services needs in bivariate analyses. As shown in Table 3, in multivariate models, TA remained associated with use of a greater number of ASO services in the past year [b = 2.0 (0.5), $p <.0001$], and a fewer number of unmet service needs [b = −1.2 (0.5), $p <.05$], above the effects of covariates. Of the covariates, only time since diagnosis was significant in the multivariate model: participants who were more recently diagnosed had a greater number of unmet social service needs [b = −0.01 (0.00), p <.01].

DISCUSSION

In combination with the results of our qualitative process evaluation showing that TA clients gained valuable treatment knowledge and positive reinforcement for adherence through TA (Mutchler et al. 2011), the findings of this quantitative analysis suggest that TA plays a key role in maintaining medication adherence. In the present study, TA clients exhibited much better adherence than did non-TA clients, with an average difference in adherence of roughly 15% as measured by both self-report and the objective electronically monitored (MEMS) data. This relationship was significant above the effects of potentially confounding socio-demographic and medical factors that could lead to self-selection of more motivated participants into TA, such as recent HIV diagnosis and higher HIV viral load. However, the significant bivariate relationship between TA and engagement in care was reduced to nonsignificance in multivariate models, suggesting that some components of TA could be strengthened to counteract powerful factors that may be contributing to care non-engagement, in addition to non-adherence, and to increase motivation for attending provider visits.

Our results help to elucidate how TA might lead to better adherence. In analyses of more proximal outcomes, clients in TA were more likely to utilize a variety of social services, and accordingly had fewer unmet needs. Interestingly, individual-level factors, i.e., patient self-advocacy and self-efficacy to adhere to treatment, were not significantly associated with being in the TA program. TA seemed to be more effective in terms of improving social and mental health factors that might otherwise set the stage for poor outcomes through intensive referral services. The narratives in our semi-structured qualitative interviews (Mutchler et al. 2011) were consistent with these quantitative data: treatment advocates, clients, and medical providers emphasized the benefits of TA in working with clients to remove barriers to adherence, including those related to subsistence needs (e.g., stable housing) and psychiatric issues (e.g., mental health, substance use), for which referrals to more intensive programs were made available.

Consistent with prior research (Oh et al. 2009; Bogart, Wagner, Galvan, & Klein 2010), African American participants had lower adherence than did White participants, and this effect persisted in multivariate models, above the effects of TA. The effects of TA could be strengthened to help overcome this disparity, perhaps through tailoring the program to address culturally relevant barriers such as medical mistrust and high levels of stress from trauma and discrimination, which have been associated with worse treatment adherence among African Americans (Bogart, Wagner, Galvan, & Banks 2010; Bogart et al. 2010; Wagner, Bogart, Galvan, Banks, & Klein 2011).

A key limitation of this study was the lack of randomization. Although our multivariate analyses controlled for potential confounders, we did not randomize clients to be in the TA program or the non-TA group; thus we do not know if the effects for adherence were due to TA, or selection bias from an unmeasured confounding characteristic related to both entry into a TA program and treatment adherence (e.g., psychological readiness to adhere). Similarly, TA could have been associated with greater social services utilization due to a confounding third variable such as an overall willingness to participate in social services programs. We attempted to minimize this bias by excluding clients who had been offered TA previously, but who had decided not to enter the program; moreover, because only 57 TA slots were available per year, only a small percentage of the ASO client base had been offered the opportunity for TA. Thus, a lack of participation in TA was likely due to a lack of awareness about the program, rather than a decision not to enter the program.

Although we attempted to recruit all eligible TA clients for the study, a small percentage of those in the program did not respond to multiple recruitment attempts. TA clients who were least likely to respond to the study recruitment materials may have been those who were also less likely to be engaged in their care and treatment, as well as in the TA program. However, overall enrollment and retention rates were very high. Monolingual Spanish-speaking clients were not included; however, more intensive clinic-based TA programming might be needed for such clients, who may have language comprehension difficulties and a need for advocacy within the patient-provider interaction. Results may not generalize to all clients in TA programs or to clients of other organizations. In addition, participants were recruited from one ASO, and we were unable to attract a sufficient number of women for the evaluation. For more statistical power in detecting program effects, future non-randomized evaluations of small programs could focus more resources on recruiting equal numbers of program and non-program participants, possibly through multiple sites with similar programs. In similar research with small sample sizes, program participants could be matched on key socio-demographic characteristics with non-program participants, to increase the chances that the two groups are drawn from similar populations.

In sum, our results suggest that TA is a promising community-based intervention to support adherence to treatment. A randomized controlled trial of TA is warranted to confirm these results. In times of scarce resources and shrinking budgets for HIV care and prevention, policymakers and community must make difficult decisions regarding which programs merit funding. Researchers should work with community partners to amass the empirical support needed to inform policy decisions. Community-based research such as this study can help to inform policymakers regarding evidence-based programs that have effects on the public health.

Acknowledgments

This research was supported by R21 NR010284 and R01 MD003964.

We thank the AIDS Project Los Angeles treatment advocacy community advisory board and interns and volunteers, including Philicia Castillo and Caleigh Douglass.

References

AARDEX Inc. Medication Event Monitoring System. Zurich; Switzerland: 2005.

Arnsten JH, Demas PA, Grant RW, Gourevitch MN, Farzadegan H, Howard AA, Schoenbaum EE. Impact of active drug use on antiretroviral therapy adherence and viral suppression in HIV-infected drug users. Journal of General Internal Medicine. 2002; 17(5):377–81. [PubMed: 12047736]

Ashman JJ, Conviser R, Pounds MB. Associations between HIV-positive individuals' receipt of ancillary services and medical care receipt and retention. AIDS Care. 2002; 14(suppl 1):S109–S118. [PubMed: 12204145]

Bangsberg DR. Less than 95% adherence to nonnucleoside reverse-transcriptase inhibitor therapy can lead to viral suppression. Clinical Infectious Diseases. 2006; 43(7):939–941. [PubMed: 16941380]

Bangsberg DR, Acosta EP, Gupta R, Guzman D, Riley ED, Harrigan PR, Parkin N, Deeks SG. Adherence-resistance relationships for protease and non-nucleoside reverse transcriptase inhibitors explained by virological fitness. AIDS. 2006; 20(2):223–31. [PubMed: 16511415]

Bangsberg DR, Hecht FM, Charlebois ED, Zolopa AR, Holodniy M, Sheiner L, Bamberger JD, Chesney MA, Moss A. Adherence to protease inhibitors, HIV-1 viral load, and development of drug resistance in an indigent population. AIDS. 2000; 14(4):357–366. [PubMed: 10770537]

Blair JM, McNaghten AD, Frazier EL, Skarbinski J, Huang P, Heffelfinger JD. Clinical and Behavioral Characteristics of Adults Receiving Medical Care for HIV Infection --- Medical Monitoring Project, United States, 2007. MMWR Surveillance Summaries. 2011; 60(11):1–20.

Bogart LM, Uyeda KE. Community-based participatory research: partnering with communities for effective and sustainable behavioral health interventions. Health Psychology. 2009; 28(4):391–3. [PubMed: 19594261]

Bogart LM, Wagner G, Galvan FH, Banks D. Conspiracy beliefs about HIV are related to antiretroviral treatment nonadherence among African American men with HIV. Journal of Acquired Immune Deficiency Syndromes. 2010; 53(5):648–655. [PubMed: 19952767]

Bogart LM, Wagner GJ, Galvan FH, Klein DJ. Longitudinal relationships between antiretroviral treatment adherence and discrimination due to HIV-serostatus, race, and sexual orientation among African-American men with HIV. Annals of Behavioral Medicine. 2010; 40(2):184–190. [PubMed: 20552416]

Brashers DE, Haas SM, Neidig JL. The patient self-advocacy scale: measuring patient involvement in health care decision-making interactions. Health Communication. 1999; 11(2):97–121. [PubMed: 16370972]

Chan D, Absher D, Sabatier S. Recipients in need of ancillary services and their receipt of HIV medical care in California. AIDS Care. 2002; 14(suppl 1):S73–S83. [PubMed: 12204143]

Chesney MA, Ickovics JR, Chambers DB, Gifford AL, Neidig JL, Zwickl B, Wu AW. 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(3):255–266. [PubMed: 10928201]

Conviser R, Pounds MB. The role of ancillary services in client-centred systems of care. AIDS Care. 2002; 14(suppl 1):S119–S131. [PubMed: 12204146]

Cunningham WE, Andersen RM, Katz MH, Stein MD, Turner BJ, Crystal S, Zierler S, Kuromiya K, Morton SC, St Clair P, Bozzette SA, Shapiro MF. The impact of competing subsistence needs and barrier on access to medical care for persons with human immunodeficiency virus receiving care in the United States. Medical Care. 1999; 37(12):1270–1281. [PubMed: 10599608]

Cunningham WE, Rana HM, Shapiro MF, Hays RD. Reliability and validity of self-report CD4 counts-in persons hospitalized with HIV disease. Journal of Clinical Epidemiology. 1997; 50(7): 829–35. [PubMed: 9253395]

Gardner E, McLees M, Steiner J, Del Rio C, Burman W. The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. Clinical Infectious Diseases. 2011; 52(6):793–800. [PubMed: 21367734]

Gardner LI, Marks G, Craw J, Metsch L, Strathdee S, Anderson-Mahoney P, del Rio C. Antiretroviral Treatment Access Study Group. Demographic, psychological, and behavioral modifiers of the Antiretroviral Treatment Access Study (ARTAS) intervention. AIDS Patient Care STDS. 2009; 23(9):735–42. [PubMed: 19645619]

Gardner LI, Metsch LR, Anderson-Mahoney P, Loughlin AM, del Rio C, Strathdee S, Sansom SL, Siegal HA, Greenberg AE, Holmerg SD. Antiretroviral Treatment and Access Study Group. Efficacy of a brief case management intervention to link recently diagnosed HIV-infected persons to care. AIDS. 2005; 19(4):423–431. [PubMed: 15750396]

Giordano TP, White AC, Sajja P, Graviss EA, Arduino RC, Adu-Oppong A, Lahart CJ, Visnegarwala F. Factors associated with the use of highly active antiretroviral therapy in patients newly entering care in an urban clinic. Journal of Acquired Immune Deficiency Syndromes. 2003; 32(4):399–405. [PubMed: 12640198]

HIV Epidemiology Program. HIV/AIDS semi-annual surveillance summary. Los Angeles County Department of Public Health; 2010. p. 1-33.

Israel, BA.; Eng, E.; Schulz, AJ.; Parker, EA. Methods in community-based participatory research for health. San Francisco, CA: Jossey-Bass; 2005.

Katz MH, Cunningham WE, Fleishman JA, Andersen RM, Kellogg T, Bozzette SA, Shapiro MF. Effects of case management on unmet needs and utilization of medical care and medications among HIV-infected persons. Annals of Internal Medicine. 2001; 135(8):557–565. [PubMed: 11601927]

Lo W, MacGovern T, Bradford J. Association of ancillary services with primary care utilization and retention for patients with HIV/AIDS. AIDS Care. 2002; 14(suppl 1):S45–S57. [PubMed: 12204141]

Magnus M, Schmidt N, Kirkhart K, Schieffelin C, Fuchs N, Brown B, Kissinger PJ. Association between ancillary services and clinical and behavioral outcomes among HIV-infected women. AIDS Patient Care STDS. 2001; 15(3):137–45. [PubMed: 11313026]

Messeri PA, Abramson DM, Aidala AA, Lee F, Lee G. The impact of ancillary HIV services on engagement in medical care in New York City. AIDS Care. 2002; 14(suppl 1):S15–S29. [PubMed: 12204139]

Mugavero MJ, Lin HY, Allison JJ, Willig JH, Chang PW, Marler M, Raper JL, Schumacher JE, Pisu M, Saag MS. Failure to establish HIV care: characterizing the “no show” phenomenon. Clinical Infectious Diseases. 2007; 45(1):127–130. [PubMed: 17554713]

Mutchler MG, Wagner G, Cowgill BO, McKay T, Risley B, Bogart LM. Improving HIV/AIDS care through treatment advocacy: going beyond client education to empowerment by facilitating client-provider relationships. AIDS Care. 2011; 23(1):79–90. [PubMed: 21218280]

Oh DL, Sarafian F, Silvestre A, Brown T, Jacobson L, Badri S, Detels R. Evaluation of adherence and factors affecting adherence to combination antiretroviral therapy among White, Hispanic, and Black men in the MACS cohort. J Acquir Immune Defic Syndr. 2009; 52(2):290–3. [PubMed: 19521251]

Ortego C, Huedo-Medina TB, Llorca J, Sevilla L, Santos P, Rodríguez E, Warren MR, Vejo J. Adherence to Highly Active Antiretroviral Therapy (HAART): A meta-analysis. AIDS Behav. 2011 Epub.

Paterson DL, Swindells S, Mohr JA, Brester M, Bergis EN, Squier C, Wagener MM, Singh N. Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. Annals of Internal Medicine. 2000; 133(1):21–30. [PubMed: 10877736]

Rumptz MH, Tobias C, Rajabiun S, Bradford J, Cabral H, Young R, Cunningham WE. Factors associated with engaging socially marginalized HIV-positive persons in primary care. AIDS Patient Care STDS. 2007; 21(suppl 1):S30–S39. [PubMed: 17563288]

Sherer R, Stieglitz K, Narra J, Jasek J, Green L, Moore B, Shott S, Cohen M. HIV multidisciplinary teams work: support services improve access to and retention in HIV primary care. AIDS Care. 2002; 14(suppl 1):S31–S44. [PubMed: 12204140]

Shuter J, Sarlo JA, Kanmaz TJ, Rode RA, Zingman BS. HIV-infected patients receiving lopinavir/ritonavir-based antiretroviral therapy achieve high rates of virologic suppression despite adherence rates less than 95%. Journal Of Acquired Immune Deficiency Syndromes. 2007; 45(1):4–8. [PubMed: 17460469]

Simoni JM, Kurth AE, Pearso CR, Pantalone DW, Merrill JO, Frick PA. Self-report measures of antiretroviral therapy adherence: a review with recommendations for HIV research and clinical management. AIDS and Behavior. 2006; 10(3):227–245. [PubMed: 16783535]

Soto T, Bell J, Pillen M. HIV/AIDS Treatment Adherence Health Outcomes and Cost Study Group. Literature on integrated HIV care: a review. AIDS Care. 2004; 16(suppl 1):S43–S55. [PubMed: 15736821]

Teshale, E.; Kamimoto, L.; Harris, N.; Li, J.; Wang, H.; McKenna, M. Estimated number of HIV-infected persons eligible and receiving HIV antiretroviral therapy, 2003--United States. 12th Conference on Retroviruses and Opportunistic Infections; Boston, MA. 2005.

Van Servellen G, Nyamathi A, Carpio F, Pearce D, Garcia-Teague L, Herrera G, Lombardi E. 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. AIDS Patient Care STDS. 2005; 19(11):745–59. [PubMed: 16283835]

Viswanathan, M.; Ammerman, A.; Eng, E.; Garlehner, G.; Lohr, KN.; Griffith, D.; Rhodes, S.; Samuel-Hodge, C.; Maty, S.; Lux, L.; Webb, L.; Sutton, SF.; Swinson, T.; Jackman, A.; Whitener, L. Evidence Report/Technology Assessment. Rockville, MD: Agency for Healthcare Research and Quality; 2004. Community-based participatory research: Assessing the evidence.

Wagner GJ, Bogart LM, Galvan FH, Banks D, Klein DJ. Discrimination as a key mediator of the relationship between posttraumatic stress and HIV treatment adherence among African American men. Journal of Behavioral Medicine. 2011 Epub.

Walsh JC, Mandalia S, Gazzard BG. Responses to a 1 month self-report on adherence to antiretroviral therapy are consistent with electronic data and virological treatment outcome. AIDS. 2002; 16(2): 269–277. [PubMed: 11807312]

Table 1

Sample Characteristics Overall, and by Treatment Advocacy (TA) Group

	Overall	**TA Clients**	**Non-TA Clients**
Male Gender (%)	87%	86%	87%
Age [M (SD)]	43.2 (8.3)	43.0 (9.1)	43.3 (8.0)
Gay/Bisexual (%)	75%	67%	79%
Annual Income ≤$10,000	68%	61%	71%
Education ≤High School*	41%	25%	48%
Stable Housing Status	64%	75%	60%
Race/Ethnicity (%)[a]			
African American	40%	31%	44%
Asian	2%	6%	0%
Latino	24%	33%	20%
Native American	10%	14%	8%
Pacific Islander	2%	3%	1%
White	34%	33%	34%
Other	5%	11%	2%

* $p < .05$ for the difference between the TA and non-TA groups

[a] Percentages for race/ethnicity sum to greater than 100% because participants could endorse more than one race/ethnicity.

Table 2

Multivariate regression models testing adjusted effects of treatment advocacy (TA) on adherence and engagement in care.

	Adherence: Electronically Monitored (2 Weeks) n = 54 b (SE)	**Adherence: Self-Report (Month) n = 81 b (SE)**	**Engagement in Care (3 Months) N = 115 OR (95%CI)**
TA Client	14.31 (5.52)*	13.07 (5.58)*	2.64 (0.67 –10.36)
Covariates			
Months Since Diagnosis	0.01 (0.04)	0.00 (0.03)	1.00 (0.99– 1.01)
Viral Load Undetectable	4.05 (7.24)	17.32 (6.60)*	1.91 (0.72 – 5.06)
CD4 Count <200	−20.02 (8.68)*	−5.62 (7.10)	-----
Low Education	1.81 (5.30)	0.29 (5.38)	1.06 (0.40 – 2.86)
Black Race	−13.55 (6.04)*	-----	-----
Latino Ethnicity	−0.57 (7.12)	-----	-----

*$p < .05$

Table 3

Multivariate regression models testing adjusted effects of treatment advocacy (TA) on number of ASO services used and unmet social service needs.

	Number of ASO Services Used, Past Year (n = 113) b (SE)	**Number of Unmet Social Service Needs (n = 114) b (SE)**
TA Client	2.05 (0.49)***	−1.17 (0.49)*
Covariates		
Months Since Diagnosis	0.00 (0.00)	−0.01 (0.00)**
Viral Load Undetectable	0.31 (0.43)	−0.28 (0.43)
Low Education	0.09 (0.43)	−0.16 (0.44)
Age	-----	−0.04 (0.03)
Low Income (<$10K/year)	-----	0.61 (0.46)

[*] p < .05

[**] p<.01

[***] p<.001