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Predictors of Screening for AIDS Clinical Trials Among African Americans and Latino/Hispanics Enrolled in an Efficacious Peer-Driven Intervention: Uncovering Socio-Demographic, Health, and Substance Use-Related Factors That Promote or Impede Screening

Marya Gwadz[*], **Charles M. Cleland**[*], **Noelle R. Leonard**[*], **Amanda S. Ritchie**[*], **Angela Banfield**[*], **Marion Riedel**[†], **Pablo Colon**[*], and **Donna Mildvan**[‡]

[*]Center for Drug Use and HIV Research, New York University College of Nursing, New York, New York

[†]School of Social Work, Columbia University, New York, New York

[‡]Division of Infectious Diseases, Beth Israel Medical Center, New York, New York

Introduction

People of color are greatly over-represented among the population of persons living with HIV/AIDS (PLHA) in the United States. However, they are significantly under-represented in AIDS clinical trials (ACTs), with the greatest disproportionality found among African Americans living with HIV/AIDS [1–3]. For example, African Americans currently comprise approximately 50% of all people living with HIV/AIDS but only 30% of those enrolled in ACTs [4,5]. This low enrollment of people of color in ACTs raises questions about the applicability of research findings to the populations most affected by HIV/AIDS, and denies individual PLHA of color the opportunity to contribute to and possibly benefit from participation in biomedical studies and trials [6,7]. Although the range of barriers that PLHA of color experience in accessing ACTs has been described in the literature [8–11], including individual-, social-, and structural-level impediments, intervention efforts have only recently been directed toward this health disparity. Screening is the first step in the process of enrolling in ACTs [12]. Yet PLHA of color are less likely to be referred to screening than their White peers [1, 11,13,14]. Our research team recently evaluated one of the first behavioral interventions to reduce barriers to screening for ACTs among African American and Latino/Hispanic PLHA. In a randomized controlled trial (RCT), we found that a targeted peer-driven intervention (PDI) called the “ACT2 Project” was highly efficacious in increasing screening rates for this population compared to a control intervention [12]. Indeed, a preliminary analysis showed that 46% in an intervention arm and <2% in a control arm screened for ACTs (AOR=55.0; z=5.49, $p < .0001$) [12], which

Corresponding Author: Marya Gwadz. Ph.D., New York University College of Nursing, 726 Broadway, 10th Floor, New York, NY 10003, office) 212-992-7147, fax) 212-995-3143, Marya.gwadz@nyu.edu.

was supported upon final analysis (56% screened in the intervention arm [N=198/351], compared to <5% in the control arm) [15].

The field of intervention research has focused mainly on evaluating intervention efficacy or effectiveness, and has placed less emphasis on identifying factors that moderate or mediate intervention efficacy or effectiveness [16]. Moderators are factors that may positively or negatively influence an intervention's effects but which either cannot be changed (e.g., race/ethnicity, historical factors) or are not targeted for change in a particular intervention (e.g., substance use, socioeconomic status). Yet understanding an intervention's moderators can guide efforts to implement an efficacious intervention, as well as the development of future, more efficacious programs, and also can inform new research questions [17]. This is because even a highly potent intervention may work more efficiently for some demographic groups than others, and therefore, such an analysis highlights which subgroups in a population are most likely to require additional support or services to successfully achieve the study's endpoint. An exploration of such predictors of intervention efficacy may be particularly relevant for populations such PLHA of color, which tend to be diverse with respect to socio-demographic and clinical characteristics [7]. The present study seeks to advance our understanding of interventions to reduce racial/ethnic health disparities by uncovering a set of factors that promoted or impeded the efficacy of a targeted PDI to increase screening for ACTs among PLHA of color. In the following section we briefly describe which socio-demographic and background factors are known to promote or reduce rates of participation in ACTs generally, independent of intervention efforts. These factors constitute a reasonable starting point for the exploration of moderators of the ACT2 PDI's effects, even if the intervention has effects on ACT participation among those with one or more previously identified barrier. However, we do not know whether these previously identified factors, in the presence of a strong intervention, have effects on ACT participation similar to the effects observed in the absence of intervention.

Factors Influencing Participation in ACTs

Race/Ethnicity and Discrimination—African American PLHA are greatly underrepresented, and Latino/Hispanic PLHA tend to be modestly under-represented in ACTs [1,2,18,19]. The relationship between under-representation and race is complex, but the literature on barriers to clinical trials other than for HIV/AIDS indicates that racial discrimination is a primary factor associated with poor access to trials [20], and this may also be the case in ACTs [21].

Gender and Sexual Orientation—While earlier studies found that women were less likely to participate in trials than men [18], more recent research suggests that female gender is not a major barrier to trials [2,7,19]. Among men, men who have sex with men (MSM) have been found to enroll in ACTs at higher rates than heterosexuals [2,7,19].

Alcohol and Drug Use—Substance use, including injection and non-injection drug use and alcohol use, is another important set of barriers to ACTs [2,18]. Substance users are less likely to be included in ACTs than their non-using peers largely because of exclusion

criteria that may reflect adherence and drug interaction concerns on the part of study sponsors, providers, and clinical trials sites [22].

Health and Other Factors—Individuals in stable health and for whom antiretroviral therapy is not indicated are typically less interested in ACTs [7,19]. Further, low health literacy appears to interfere with ACT participation [2,23]. Mental health problems may impede access to ACTs [24–27] (Mental health factors can be modified in interventions but were not a direct target for change in the ACT2 PDI.) Last, Gifford and colleagues [2] found that residential location can affect participation, where residing in closer proximity to a trial site increases the chances one will participate in ACTs.

Aims

The present paper sought to identify a set of factors – either unmodifiable or that were not directly targeted in this intervention – that promoted or impeded the efficacy of a potent PDI described in previous research [12]. Specifically, we examined whether (a) socio-demographic characteristics (race/ethnicity, gender, sexual orientation, borough of residence within New York City [where Manhattan is the most service-rich borough [28,29]], and racial/ethnic discrimination), (b) substance use (frequency of use and past and current injection drug use), (c) health characteristics (physical and mental health status, health literacy), and (d) intervention "dose" variables (e.g., whether the participant attended all intervention sessions) predicted participation in screening for ACTs in the context of an efficacious intervention.

Methods

Description of the Study

As noted above, the aim of the paper was to understand factors that predicted screening in the context of an efficacious intervention program [12]. The sample for the present study, therefore, was made up of participants in the larger study's intervention arm (N=351), of which 56% were screened for ACTs, as noted above (N=198/351). In light of the present paper's aims, we did not include participants assigned to control arm (N=189) because they did not participate in the intervention. Procedures were approved by the Institutional Review Boards at the collaborating sites and by the participating community-based organizations. The intervention curriculum is available from the first author. In the following sections we briefly describe the methods used in the larger study.

Sample Recruited for the Larger Study

A total of 540 PLHA were recruited through respondent-driven sampling (RDS [30]) in New York City between June 2008 and April 2010. Recruitment began with 49 initial seeds nominated by staff at two community-based organizations serving PLHA located in the borough of Manhattan. Initial seeds were active clients at the two organizations, aged 18 years or older, HIV-infected (confirmed by medical documentation), of African-American or Latino racial/ethnic background, willing to recruit HIV-infected peers, able to conduct research activities in English, and not currently enrolled in an ACT.

Design and ACT2 PDI Description

Initial seeds were randomly assigned at a 2:1 ratio to either a PDI or a health education control condition. The PDI was made up of 6 hours of structured activities over three group sessions (5.5 hours) and one individual session (30 minutes) plus brief "liaison" contacts as needed during the screening process to resolve practical barriers. Those in the PDI arm also had the opportunity to educate up to three peers on core intervention messages pertaining to ACTs. Peer education experiences were considered a "dose" of intervention for both the educator and the peer [12,31] Those in the control arm received a time- and attention-matched health education intervention conducted in three small group sessions (6 hours of structured activities). Participants in the control arm recruited peers for the study but did not educate them. Participants received compensation of $25 for each intervention session and $15–25 for each peer recruited/educated. Peers recruited into the study were assigned to the same intervention arm as the individual who recruited him/her. Thus the design is equivalent to a cluster randomized controlled trial. A total of 351/540 participants were assigned to the PDI arm, and 189/540 to the control arm. The larger study's primary endpoint was screening for ACTs to the point of determining eligibility. Importantly, the screening endpoint was modeled on a "real world" screening encounter where participants took the initiative to make and attend the screening appointment, and were not provided with compensation for the screening visit or visits.

Assessments

Participants were assessed at three time points: Baseline, and 16 and 52-weeks post-baseline. These interviews lasted approximately one hour and were administered by trained staff on laptop computers and consisted of computer-assisted personal interview (CAPI) and audio, computer-assisted self-interviewing (ACASI) segments [32]. Participants received compensation of $25 for each interview.

Measures

Sociodemographic Characteristics—Age, race/ethnicity, gender, sexual orientation, and borough of residence (out of New York City's five boroughs) were assessed using a structured instrument.

Experiences of Discrimination—Participants were given the Experiences of Discrimination (EOD) measure [33], a multi-item instrument with high reliability and validity that assesses experiences of racial discrimination in a variety of situations (Cronbach's $\alpha = .84$). Across the nine situations, participants indicated the frequency with which discrimination was experienced, ranging from 0=never to 3=four or more times. A summary variable was constructed by averaging over the nine situations.

Substance Use Frequency—Participants were asked about the frequency of alcohol and drug use in the previous three months. Drug use items covered heroin, cocaine, crack, methadone not prescribed by a doctor, marijuana, amphetamines, prescription drugs not prescribed by a doctor, any other injected substance, and any other drug or substance not specifically mentioned in other items. Frequencies ranged from 0=never to 8=ten or more times a day almost every day. Alcohol frequency (0–8) was used as a stand-alone item, and

drug use frequency (0–8) was summarized as the frequency of use of the most frequently used substance. Other items asked about both lifetime injection drug use and injection drug use in the previous three months. Based on these items, participants were classified as never, past, or current injection drug users [34].

HIV-Related Physical Health Indices—HIV-related physical health indices were assessed with the HIV Cost and Services Utilization Study (HCSUS) measure including self reported health status on a five point Likert-type scale (poor, fair, good, very good, excellent), year of first HIV diagnosis, CD4+ count, viral load levels (re-coded as undetectable viral load; yes/no), and antiretroviral (ART) status (never took ART, past ART use, current ART use) [35].

Mental Health—Mental health symptoms were assessed with the Brief Symptom Inventory (BSI), a 53-item reliable and valid self-report symptom inventory rated on a 5 point Likert scale with a higher score indicating more distress (Cronbach's $\alpha = .96$). Items were used to create a composite score, the *Global Severity Index*, ranging from 0–4 with higher values indicating more mental health symptoms and greater intensity of distress [36].

Rapid Estimate of Adult Literacy in Medicine—Participants were given the Rapid Estimate of Adult Literacy in Medicine (REALM) and asked to pronounce the following eleven health-related terms: fat, flu, pill, osteoporosis, allergic, jaundice, anemia, fatigue, directed, colitis, and constipation [37]. Correct pronunciation of these words indicates greater health-related literacy. The REALM has been widely used and has been found to have excellent reliability and concurrent validity with respect to standardized reading tests (Cronbach's alpha $\alpha = .84$). The proportion of terms pronounced correctly (0–1) was used to summarize health literacy.

Intervention "Dose"—Intervention dose was assessed including whether the participant attended all intervention sessions (yes/no) and the number of peers recruited and educated (range 0–3).

Screening To the Point of Determining Eligibility—Screening to the point of eligibility (yes/no) was assessed by self-report as a component of the assessment battery and also verified using a separate data source collected on those who presented for screening at the collaborating hospital site and other clinical trials sites, as appropriate. Among the larger sample, almost all participants (94.9%; N=333/540) completed the 16-week follow-up interview, and 89.7% (n=315/540) completed the 52-week follow-up interview. For the twelve participants (3.4%) with neither a 16-week nor a 52-week follow-up interview, the screening outcome was based only on our check of clinical trials unit records. Thus all reports of screening were externally verified.

Data Analysis

We summarized sample characteristics using descriptive statistics and used multivariable logistic regression analysis in Stata (version 12) to identify predictors of screening. To take into account clustering of participants due to recruitment relationships, we used robust

estimation of standard errors. We first considered a model with all of the following potential predictors: gender, age, race/ethnicity, sexual orientation, borough of residence, frequency of racial discrimination, health literacy (REALM), antiretroviral medication use, CD4+ count, undetectable viral load, prior ACT screening, self-rating of general health, mental health global severity index (BSI), injection drug use, frequency of alcohol and drug use in the past three months, intervention session attendance, and number of recruits. Forty participants (11.4%) had missing data on one or more of the potential predictors of screening (see below). The initial multivariable logistic regression model was revised by removing CD4+ count and undetectable viral load because these two variables were far from significant and also responsible for more than half (n=23; 57.5%) of all missing data.

Results

Sociodemographic and other characteristics of the sample are described in Table I. Approximately 44% of the sample was female and the mean age was 49.4 years (SD=7.4 years). Two-thirds (65.8%) of participants were African American, and about a quarter were Latino/Hispanic (24.8%). Most (70.7%) were heterosexual. With respect to residential location, they were mainly located in three of NYC's five boroughs (two "outer boroughs," Brooklyn and the Bronx, and Manhattan), with the remaining 11.4% in Queens, Staten Island, and outside of New York City. Rates of perceived discrimination appeared relatively low (mean=0.50 on a 0–3 scale; SD=0.61). Most were currently taking ART (66.2%), and a quarter (25.2%) had never taken ART. The mean CD4+ count was 520 cells/ml (SD=607 cells/ml), and two-thirds (64.5%) reported an "undetectable" viral load. The average year of HIV diagnosis was 1994 (SD=5.8 years). Less than a quarter (23.1%) had been screened for ACTs in the past. The majority reported that health was good to excellent, and rates of mental health symptoms were relatively low (mean=0.49 on a 0–4 scale). About a third had injected drugs in their lifetimes (29.3%) and 2.6% were currently injecting drugs. Alcohol and drug frequency was, on average, low (e.g., alcohol mean=1.47 on a 0–8 scale). Most (88.3%) attended all intervention sessions and the average number of peers recruited/educated was 1.03 peers (SD=1.09 peers).

Table II shows estimates of adjusted odds ratios in the final logistic regression model after removal of CD4+ counts and viral load. (CD4+ counts and viral load were far from statistically significant predictors of screening and accounted for more than half [57.5%] of missing data.) The odds of screening were increased by residence in Brooklyn relative to Manhattan, higher mental health symptom severity, more frequent alcohol use, greater number of years since HIV diagnosis, past screening experiences, greater number of peers recruited/educated, and attendance of all intervention sessions. The odds of screening were decreased by gay or lesbian sexual orientation (relative to heterosexual), and current injection drug use (relative to never injecting).

To aid interpretation of the effects in Table II, we calculated model-predicted probabilities of screening using the *margins* and *prvalue* functions [38] in Stata. Table III shows these model-predicted probabilities of screening for the variables found to be associated with screening with at least marginal statistical significance ($p < .10$): borough of residence (Manhattan, Bronx, Brooklyn, Queens), sexual orientation (heterosexual, bisexual, gay/

lesbian), BSI Global Severity Index, the mental health index (comparing the lower and upper quartiles to aid interpretation), years since HIV diagnosis (comparing the lower and upper quartiles to aid interpretation), general health self rating (five-level Likert-type scale ranging from poor to excellent), injection drug use (never, past, current), recent alcohol frequency (never vs. about once a week), recent drug use frequency (never vs. about once a week), ART use (current, never, past use), past screening for ACTs (no/yes), number of peers recruited/educated (none vs. three), and attendance of all intervention sessions (no/yes). Predicted probabilities of screening were lowest for current injection drug users (0.27) and participants who did not receive a full dose of the intervention (0.24). Predicted probabilities of screening were highest for those: who recruited/educated more peers (0.71), had past screening experience (0.71), with the highest general health self rating (0.67), who were residing in Brooklyn (0.63), who had never been on ART (0.63), with the longest time since HIV diagnosis (0.63), with higher alcohol frequency (0.61), with higher BSI Global mental health Severity Index (0.60).

Discussion

Research on behavioral interventions has focused largely on evaluating efficacy or effectiveness, and less attention has been paid in the literature to understanding factors that are not addressed or cannot be addressed in interventions, but that nonetheless impede or foster an intervention's effects [16]. In recent past research we found in a randomized controlled trial that a PDI was highly efficacious in increasing screening rates for ACTs among African American and Latino/Hispanic PLHA – the first such intervention to our knowledge [12]. The present paper sought to uncover the socio-demographic and other unchangeable characteristics, as well as factors relevant to the population that were not targeted for change in the intervention, that either promoted or reduced screening rates among those who participated in the PDI. We believe it is important to uncover these factors, because better understanding of them can inform the implementation of intervention programs such as the ACT2 PDI in sites that seek to reduce racial/ethnic disparities in ACTs, as well as the development of future interventions to reduce racial/ethnic disparities in ACTs.

Findings from the present paper differ from the past literature on almost every index we examined. We believe this discrepancy results mainly from the fact that in past research, barriers to ACTs have been identified in observational studies, but not intervention studies. Indeed, predictors of participation in ACTs described in the context of standard efforts to engage PLHA into trials may not be the same as those that moderate the impact of an efficacious intervention. In other words, these findings highlight the fact that an intervention is a special context in which new and different predictors may emerge that are relevant to implementing and improving the intervention, but may not necessarily reveal barriers to ACTs in general. We interpret discrepancies between the existing literature and present paper in more detail below.

Race/Ethnicity and Perceived Discrimination

African American racial background did not predict lower rates of screening compared to Latinos, contrary to our hypothesis (57% of African Americans and 55% of Latinos were screened; data not shown). Nationally, African American PLHA have the greatest barriers to ACTs, including low rates of recruitment into ACTs by providers and health care settings, high levels of medical mistrust, and also the highest rates of under-representation in ACTs of any racial/ethnic group [1–3]. On the other hand, past research indicates that African Americans are willing, at least in theory, to participate in ACTs if asked [3,8,39]. Although researchers and providers often assume African American PLHA are not interested in ACTs [11], the present study indicates they are highly amenable to screening in the context of a culturally targeted intervention, and as likely to do so as Latinos, even though Latinos are considered to have fewer barriers to ACTs. Further, the lack of racial/ethnic differences provides support for the ACT2 PDI's approach of targeting African Americans and Latinos in a single intervention, rather than developing separate interventions for the two racial/ethnic groups. (The ACT2 PDI takes the approach of addressing the underlying shared barriers to ACTs associated with racial/ethnic minority status, regardless of whether one is African American or Latino [e.g., exclusion, lack of knowledge, medical mistrust, negative norms, and structural barriers], while not assuming cultural homogeneity across these two groups [12].) Moreover, we did not find that general perceived discrimination was a predictor of screening, contrary to hypotheses, and experiences of discrimination appeared to be relatively modest in this sample. One possibility is that the measure of discrimination, which was not specific to HIV, was insufficiently sensitive to experiences of discrimination faced by this population. It is also possible that this population is buffered to a certain extent from experiences of discrimination by virtue of their having adapted to living with HIV while being embedded in a set of supportive and health services, which is fairly common for PLHA in NYC, a setting with a large and mature HIV epidemic and substantial network of services for PLHA [40–42].

Geography

Residing a greater distance from the screening site was associated with screening, in contrast to the literature. Although the screening site was located in Manhattan, those residing in boroughs outside of Manhattan were more likely to be screened than those residing within Manhattan. We interpret this as a response to both the local service context and the availability of public transportation. ACTs do not provide primary health care but involvement in ACTs allows PLHA access to a high level of care and the most up-to-date HIV treatment information, as well as potential access to the newest treatment available. Manhattan is the most service-rich borough with approximately 32,811 PLHA, 15 "Designated AIDS Centers" (DACs; which are state-certified, hospital-based programs that serve as the hubs for a continuum of hospital and community-based care for PLHA) and close to 40 AIDS service organizations over a relatively small geographical area (23.7 sq. miles) [28,29,43,44]. The remaining boroughs, in contrast, comprise geographically larger areas, and have a substantially lower service site-to-PLHA ratio[43]. For example, Queens has 15,538 PLHA, 3 DACs and 3 AIDS service organizations [28,29,43]. One possibility is that many PLHA living in an outer borough receive primary care near their residence, but were motivated to travel to Manhattan to explore ACTs. Moreover, it is possible that PLHA

may be more willing to travel distances to explore ACTs when they reside in areas with a lower density of providers and service settings. An alternate interpretation is that PLHA of color prefer service settings outside their neighborhoods as a means of protecting confidentiality and thus are willing to travel to explore HIV-related resources. It is worth noting, however, that New York City has a public transportation system that allows individuals to travel easily over large distances, which may not be the case in other urban areas. Nonetheless, this finding is notable because it highlights the fact that PLHA will travel to explore ACTs if motivated to do so.

Sexual Minority Status

The past literature showed that MSM are involved in ACTs at higher rates than heterosexuals, yet in the present study we found that sexual minorities were less likely to be screened than their heterosexual peers. However, this past literature on enrollment of MSM versus heterosexuals has included primarily White participants [45], and MSM of color such as those in the present study may experience considerably different attitudes toward and opportunities to access ACTs than their White MSM counterparts. Indeed, this finding may reflect the multiple stigmas experienced by PLHA of color who are also sexual minorities [46]. In studies of HIV care, for example, experiences of stigma among sexual minorities with HIV, many of whom are persons of color, are pervasive and appear to interfere with the receipt of medications and health care [47,48]. Thus sexual minority PLHA of color may need extra time and support in the screening process in comparison to their heterosexual peers.

Mental Health

Higher rates of mental health symptoms were associated with screening, in contrast to the literature. Those with higher levels of mental health symptoms were somewhat more likely than those with lower symptoms to be screened (predicted probabilities were 0.60 and 0.52 respectively). It is possible that PLHA of color with serious mental health symptoms may be more motivated to access resources and services in the hopes of ameliorating distress. Yet we did not examine the specific types of distress experienced by participants (e.g. depressive, anxious, phobic symptoms). This is relevant, as depression is typically more likely to impede service use while anxiety may increase motivation to access services [49]. This particular barrier can be further explored in future research. Yet is it worthwhile to highlight that mental health distress does not necessarily preclude individuals from accessing ACT screening, and those with lower symptoms may have somewhat less motivation to access ACTs and thus require additional services or support.

Health Indicators

Health status and ART were not predictors of screening at statistically significant levels, in contrast to the literature. The literature suggests that participants with poor or failing health status are more likely to enter ACTs, perhaps as a means to bolster health, although the present study did not support this finding. We found, at marginally statistically significant levels, that those in better health were more likely to be screened. It is possible that in this sample of older PLHA with long HIV histories that those in better health are more adherent to health care and medications, and more interested in new resources such as ACTs. This

suggests that those with the worst health status may require additional support and services to access screening. Further, contrary to hypotheses, we did not find that ART status predicted screening at a statistically significant level, although data suggested at marginally significant levels that ART naïve participants were more likely to be screened than participants currently talking ART, with those who had stopped ART having the lowest predicted probability of screening. This high probability of screening among ART naïve participants is encouraging, as many trials are designed specifically for the treatment-naïve [7]. On the other hand, PLHA who have stopped ART are vulnerable to poor health outcomes and likely have a number of barriers to ACT screening. Murphy and colleagues [50] found that stopping ART was often a function of low HIV health literacy, medication side effects, medical mistrust, or a breach in the patient-provider relationship. Thus PLHA who have stopped ART may be less likely to be screened due to past negative experiences with ART and low motivation to reinitiate ART, as many ACTs do involve taking ART. Yet not *all* ACTs involve ART, and screening for ACTs is still appropriate for PLHA who do not wish to take ART, as some ACTs prevent and treat the opportunistic infections and cancers associated with AIDS, and reconstitute HIV-damaged immune systems [5] including with therapeutic vaccines and complementary and alternative therapies [51]. PLHA who have stopped ART may therefore need additional support to understand the diversity of ACTs potentially available to them, including ACTs that do not involve ART. Last, in contrast to the literature, health literacy did not predict screening in this sample.

The number of years since HIV diagnosis predicted screening, where those living with HIV longer were more likely to be screened. Those with longer histories of HIV infection have had a greater opportunity for the development of acquired resistance or for drug intolerance, narrowing their treatment options [52]. As a result, an individual's interest in ACTs as a means of accessing new types of ART may increase over time. Individuals diagnosed longer also have had a greater period of time to adapt to their diagnoses and medication regimens[53], and may therefore be more comfortable with ACTs compared to those who are still adapting to the condition. Thus newly diagnosed individuals may require more time and attention to achieve ACT screening compared to those with a longer HIV history. Last, approximately a quarter of participants had been screened for ACTs in the past, and these individuals were significantly more likely to be screened during the present study compared to those never screened. This suggests PLHA of color find the experience of screening for ACTs to be a positive experience, and are willing to repeat it. Although the predicted probability of screening among those without prior screening experience also was substantial (0.58), individuals with no prior screening experience may benefit from additional support and intervention in order to increase their access to screening.

Substance Use

Substance use had a mixed effect on screening. The literature suggests that substance use, whether current or historical, is a serious barrier to ACTs. In the present study, drug use frequency was not a predictor of screening at a statistically significant level, although data suggest those with no drug use in the recent period had a higher predicted probability of screening compared to those with at least weekly use (0.61 vs. 0.54), consistent with the literature. Unexpectedly, however, higher alcohol frequency was associated with screening

where those with at least weekly alcohol use were somewhat more likely to be screened compared to those with no alcohol use (0.61 vs. 0.54). Thus alcohol use does not necessarily interfere with screening, perhaps because alcohol is less stigmatized than drugs. As would be expected, current injection drug use was a barrier to screening. Those with current injection drug use were very unlikely to be screened, perhaps reflecting patients' own realistic assessments that ACTs might not be appropriate for them, or that they would not be found eligible as a function of their substance use patterns. Some individuals who inject drugs, even at a high frequency, do successfully participate in ACTs, but it is not common for injection drug users to be enrolled in ACTs [18].

Intervention Dose and Components

The ACT2 PDI is a multi-component program that seeks to simultaneously address individual, attitudinal, social, and structural barriers to ACT screening [12]. The probability of screening without the intervention is very low, while attending all four intervention sessions substantially increases the chances of screening, and educating peers also increases the probability of screening. The present paper provides additional support for the utility of this multi-component, multi-level peer-driven intervention approach.

Generalizability

We expect these findings to generalize to similar PLHA participating in similar behavioral interventions. Because the PDI was highly efficacious in increasing screening rates among a diverse sample of African-American and Latino/Hispanic PLHA, and because it is currently the only intervention with considerable potential to address racial/ethnic disparities in ACT screening, the results could apply to a broad spectrum of PLHA among whom disparities in ACT screening and participation are now a significant challenge.

Limitations

While we considered a number of potential predictors of screening across a range of domains, there are obviously many other potential sociodemographic and health-related predictors of screening for ACTs that were not considered, such as co-occurring medical conditions and satisfaction with care. Also, the sample size precluded consideration of interactive effects of two or more variables, and it is possible that the effects of certain predictors depend in complex ways on other factors. Last, screening is the necessary first step toward enrollment in ACTs, and rates of enrollment into studies will be examined in future papers.

Implications

The study has a number of implications for addressing ACT disparities. For over two decades there has been great interest at the National Institutes of Health and among HIV scientists in reducing racial/ethnic disparities in ACTs [11,54–56]. The present study targets a vulnerable population and under-studied area of research and identifies a number of characteristics that impede access to ACTs, even in the context of an efficacious intervention, which signal the need for targeted strategies for and more research to better understand these characteristics and how they can be ameliorated. Although the ACT2 PDI

was moderately sensitive to some of the factors explored, it shows promise even in the most challenging subgroups identified, because ACT screening in the absence of the intervention is rare for PLHA of color.

Past research indicates three main reasons why PLHA of color are under-represented in ACTs, as we have reviewed above. First, they are less likely to be invited to screen by providers, clinical settings, and clinical trials sites. Then, when asked, they may be more likely to decline to screen or enroll than their White peers, or, if they do screen, they are more likely to face serious social, structural, and individual barriers to completing screening and enrolling into trials compared to their White peers, as this is a complex and lengthy process [8,57]. Thus, clinic and clinical trials sites have the potential to greatly reduce racial/ethnic disparities in ACTs by offering all patients regular and repeated access ACT screening, regardless of their potential eligibility or perceived interest [13], implementing interventions such as the ACT2 PDI to build patients' motivation and capabilities to screen for and join ACTs, and ameliorating the socio-demographic and other factors identified in the present paper during the screening and enrollment process in order to further increase access to ACTs for PLHA of color.

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Table I

Characteristics of People Living with HIV/AIDS in a Peer-Driven Intervention to Increase Participation in AIDS Clinical Trial Screening (N=351)

	% or Mean (SD)
Sociodemographic characteristics	
Female	44.2
Age in years	49.4 (7.4)
African American	65.8
Hispanic	24.8
Heterosexual	70.7
Gay	15.9
Lesbian	3.4
Bisexual or Other	10.0
Brooklyn	31.6
Bronx	31.1
Manhattan	25.9
Frequency of Racial Discrimination (0–3)	0.50 (0.61)
Health characteristics[a]	
Health Literacy (REALM; 0–1)	0.77 (0.25)
Current ART	66.2
Past ART	8.6
Never took ART	25.2
CD4+ count	520 (607)
Undetectable Viral Load	64.5
HIV Diagnosis Year	1994 (5.8)
Prior ACT Screening	23.1
Poor General Health	2.6
Fair General Health	24.9
Good General Health	28.6
Very Good General Health	26.3
Excellent General Health	17.7
BSI Global Severity Index (0–4)	0.49 (0.49)
Substance use	
Ever Injected Drugs	29.3
Current Inject Drugs	2.6
Alcohol Frequency Past 3 Months (0–8)	1.47 (1.88)
Drug Use Frequency Past 3 Months (0–8)	1.48 (2.14)
Intervention dose	
All Sessions Attended	88.3
Number of Peers Recruited/Educated (0–3)	1.03 (1.09)

[a]One participant was missing the general health self-rating; two were missing ART status; fourteen were missing CD4; nineteen were missing viral load; sixteen were missing year of HIV diagnosis. A total of forty participants (11.4%) were missing one or more of these variables.

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Table II

Predictors of Screening for AIDS Clinical Trials among Participants in a Peer-Driven Intervention[a]

	Adjusted Odds Ratio	Robust Standard Error	z	P>|z|	AOR 95% Confidence Interval
Female	0.62	0.2250	−1.33	0.18502	[0.30; 1.26]
Age	1.01	0.0293	0.42	0.67214	[0.96; 1.07]
Race/Ethnicity					
Hispanic vs. African-American	1.31	0.3359	1.07	0.28537	[0.80; 2.17]
Other vs. African-American	1.06	0.3336	0.18	0.85746	[0.57; 1.96]
Sexual Orientation					
Bisexual vs. Heterosexual	0.96	0.4637	−0.08	0.93615	[0.37; 2.47]
Gay or Lesbian vs. Heterosexual	0.56	0.1269	−2.54	0.01098	[0.36; 0.88]
Other vs. Heterosexual	0.24	0.2862	−1.19	0.23283	[0.02; 2.52]
Borough of Residence					
Bronx vs. Manhattan	1.67	0.7724	1.11	0.26811	[0.67; 4.13]
Brooklyn vs. Manhattan	2.15	0.7546	2.18	0.02926	[1.08; 4.28]
Staten Island vs. Manhattan	1.18	0.7034	0.28	0.78073	[0.37; 3.80]
Queens vs. Manhattan	1.50	0.8393	0.73	0.46543	[0.50; 4.49]
Outside of NYC vs. Manhattan	0.67	0.8292	−0.33	0.74481	[0.06; 7.62]
Frequency of Racial Discrimination	1.37	0.3621	1.21	0.22671	[0.82; 2.30]
Health Literacy (Realm; 0–1)	2.34	1.2192	1.64	0.10199	[0.84; 6.50]
Antiretroviral Medication					
Never vs. Current ART	1.46	0.5584	1.00	0.31647	[0.69; 3.09]
Past vs. Current ART	0.63	0.1722	−1.68	0.09368	[0.37; 1.08]
Past Screening for AIDS Clinical Trial	2.74	1.0943	2.53	0.01152	[1.25; 5.99]
General Health Self Rating					
Poor vs. Excellent	0.27	0.2048	−1.73	0.08320	[0.06; 1.19]
Fair vs. Excellent	0.49	0.1929	−1.80	0.07112	[0.23; 1.06]
Good vs. Excellent	0.57	0.2709	−1.17	0.24012	[0.23; 1.45]
Very Good vs. Excellent	0.46	0.2293	−1.56	0.11934	[0.17; 1.22]
Brief Symptom Inventory Global Severity Index	1.85	0.5579	2.04	0.04111	[1.03; 3.34]
Years Since HIV Diagnosis	1.05	0.0196	2.76	0.00580	[1.01; 1.09]

	Adjusted Odds Ratio	Robust Standard Error	z	P>|z|	AOR 95% Confidence Interval
Injection Drug Use					
Past vs. Never IDU	0.65	0.1662	−1.69	0.09055	[0.39; 1.07]
Current vs. Never IDU	0.17	0.1280	−2.37	0.01758	[0.04; 0.74]
Alcohol Frequency in the Past 3 Months (0–8)	1.11	0.0563	2.04	0.04173	[1.00; 1.23]
Drug Frequency in the Past 3 Months (0–8)	0.90	0.0566	−1.67	0.09460	[0.80; 1.02]
All Intervention Sessions Attended	6.56	2.6594	4.63	0.00000	[2.96; 14.52]
Number of Peers Recruited/Educated (0–3)	1.34	0.1684	2.32	0.02049	[1.05; 1.71]

[a] CD4 and viral load were both far from statistical significance and were removed since they contributed to a large portion of the missing data. The sample size for this final model was n=334 (95.2%).

Table III

Model-Predicted Probability of Clinical Trial Screening[a]

	Predicted Probability	95% Confidence Interval
Borough of Residence		
Manhattan	.48	[.35; .61]
Bronx	.58	[.50; .66]
Brooklyn	.63	[.55; .70]
Queens	.56	[.43; .69]
Sexual Orientation		
Heterosexual	.59	[.54; .64]
Bisexual	.58	[.40; .76]
Gay or Lesbian	.48	[.39; .57]
BSI Global Severity Index		
0.13 (*lower quartile*)	.52	[.43; .61]
0.68 (*upper quartile*)	.60	[.55; .66]
Years Since HIV Diagnosis		
Eleven (*lower quartile*)	.53	[.46; .59]
Nineteen (*upper quartile*)	.63	[.56; .70]
General Health Self Rating		
Poor	.42	[.18; .66]
Fair	.54	[.43; .64]
Good	.57	[.49; .65]
Very Good	.52	[.41; .63]
Excellent	.67	[.56; .78]
Injection Drug Use		
Never	.59	[.54; .65]
Past	.51	[.42; .60]
Current	.27	[.06; .48]
Alcohol Frequency		
Never	.54	[.46; .61]
About Once a Week	.61	[.55; .68]
Drug Frequency		
Never	.61	[.53; .69]
About Once a Week	.54	[.47; .60]
Antiretroviral Medication		
Current	.55	[.50; .61]
Never	.63	[.50; .75]
Past	.46	[.37; .55]
Past Screening for ACT		
No	.52	[.48; .56]
Yes	.71	[.58; .85]
Number of Peers Recruited/Educated		

	Predicted Probability	95% Confidence Interval
None	.50	[.39; .61]
Three	.71	[.62; .79]
Attended All Intervention Sessions		
No	.24	[.13; .35]
Yes	.61	[.55; .66]

[a]The *margins* and *prvalue* functions (Long & Freese, 2006) in version 12 of Stata were used to calculate point and interval estimates of predicted probabilities. When calculating predicted probabilities for each variable, all other variables in the model were held constant at mean values. Only variables with at least marginally significant ($p < .10$) overall effects or at least one marginally significant pairwise contrast are included.