

A Strengths-Based Case Management Intervention to Reduce HIV Viral Load Among People Who Use Drugs

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Abstract Engaging highly marginalized HIV positive people in sustained medical care is vital for optimized health and prevention efforts. Prior studies have found that strengths-based case management helps link people who use drugs to HIV care. We conducted a pilot to assess whether a strengths-based case management intervention may help people who use injection drugs (PWID) or smoke crack cocaine (PWSC) achieve undetectable HIV viral load. PWID and PWSC were recruited in Oakland, California using targeted sampling methods and referral from jails and were tested for HIV. HIV positive participants not receiving HIV care ($n = 19$) were enrolled in a pilot strengths-based case management intervention and HIV positive participants already in HIV care ($n = 29$) were followed as comparison participants. The intervention was conducted by a social worker and an HIV physician. Special attention was given to coordinating care as participants cycled through jail and community settings. Surveys and HIV viral load tests were conducted quarterly for up to 11 visits. HIV viral load became undetectable for significantly more participants in the intervention than in the

comparison group by their last follow-up (intervention participants: 32% at baseline and 74% at last follow-up; comparison participants: 45% at baseline and 34% at last follow-up; $p = 0.008$). In repeated measures analysis, PBO intervention participants had higher odds of achieving undetectable viral load over time than comparison participants ($p = 0.033$). Strengths-based case management may help this highly vulnerable group achieve undetectable HIV viral load over time.

Keywords HIV · Intervention studies · Epidemiology · Strengths-based case management · Viral load

Introduction

People who use illicit drugs, especially people who inject drugs (PWID) and people who smoke crack cocaine (PWSC), are disproportionately infected with HIV [1–4]. Access to medical care as well as initiation of and retention in antiretroviral therapy (ART) are critical to reducing morbidity and mortality from HIV. ART is associated with improved clinical outcomes, longer survival and secondary prevention of infection, including reduced HIV transmission risk at the community level [5–7]. Adherence to ART regimens and management of patients' viral load to achieve viral suppression are necessary to take full advantage of HIV treatment benefits [8, 9]. Despite the benefits of ART, people who use drugs and who are HIV-positive consistently face barriers which limit their access to ART, and the possibility of viral suppression that ART offers [10, 11].

The lives of people using illicit drugs can be challenging due to stigma, severe poverty, comorbidities (e.g. serious mental illness), and the psychological and clinical effects of the substances that are ingested [12]. These factors, in

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turn, can make it difficult for PWID and/or PWSC to access and adhere to treatment for HIV in community settings [13]. In addition, the criminalization of drug use frequently leads to repeated, short-term incarcerations and sentences of community supervision [14]. On one hand, incarceration can provide a point of access for HIV counseling, testing and treatment [15–17], and research has shown that several months or more of incarceration can provide an opportunity to more effectively initiate long-term treatment [18–20]. On the other hand, these benefits are frequently undermined by abrupt returns to community settings without coordination of care [21–23]. Interventions that address the complex and dynamic needs of PWID and/or PWSC to facilitate HIV viral suppression are necessary not only to realize the benefits of HIV treatment, but also to maximize treatment as prevention efforts.

Strengths-based case management (SBCM) is a promising, evidence-based intervention [24] to address barriers to HIV care for PWID and PWSC. The SBCM approach effectively couples (1) ‘strengths-based’ social work practice, where clients are encouraged to ascertain, leverage and build upon their strengths and capabilities in facing obstacles [25], and (2) ‘case management’ sessions focused on building relationships with clients to assess needs, identify strengths, and discuss and implement ways to overcome barriers to health care [26]. SBCM interventions have proven to be effective at linking people, including those who use illicit drugs, to HIV medical care and substance abuse treatment [26–28]. SBCM is recognized by the Centers for Disease Control and Prevention (CDC) as an effective evidence-based intervention for linkage to and retention in HIV medical care [29].

In this manuscript, we describe a pilot evaluation of a SBCM intervention to help people who use drugs to reduce their HIV viral load and achieve viral suppression.

Methods

This study is one of many studies funded as part of a NIDA- and NIMH-funded initiative to evaluate different strategies to seek, test, treat, and retain people who use drugs and have HIV. Our project involved two phases: a seek and test epidemiological observational phase which in turn helped to screen people for inclusion in an intervention evaluation phase to test and retain HIV positive people who use drugs. For the “seek and test” phase, we conducted a community-based study of PWID and PWSC in Oakland, California, U.S.A. from 2011 to 2014, that involved recruiting and screening 2424 PWID and PWSC for HIV antibodies. Potential study participants were recruited from street settings using targeted sampling methods [30, 31] and were asked to come to easily accessible, temporary

field sites in three locations close to where many people who use drugs congregate. An experienced outreach worker recruited a total of 2424 participants to be screened in a 2-year period. Eligibility criteria to be screened included being at least 18 years old and having used crack cocaine or injected drugs in the 6 months prior to interview. We used a screening instrument that obscured eligibility requirements to determine whether people were eligible. This involved 10 questions, of which 7 questions were unrelated to eligibility criteria. We obtained informed consent, conducted a baseline quantitative interview, HIV pre- and post-test counseling and HIV testing using a point-of-care HIV test. The quantitative interview was conducted in private rooms by trained interviewers reading questions out loud and recorded responses on a laptop computer using the program Blaise (Westat). Rapid testing for antibodies to HIV infection was conducted using the OraQuick ADVANCE[®] rapid HIV antibody test. We confirmed reactive results on the OraQuick test with a second point-of-care test, the Clearview STAT-PAK[®].

Participants who tested HIV antibody positive on rapid and confirmatory tests were eligible to participate in the intervention evaluation study. At this point, they underwent an additional informed consent process. Because we did not want to disrupt any existing relationships that study participants might have with HIV care providers, we screened participants for whether they were in HIV care; those who reported being in care were enrolled in the comparison group of the study. Participants who reported not currently being in HIV care were offered participation in the Project Bridge Oakland (PBO) intervention. “Not currently in HIV care” was operationalized as any of these three conditions: (1) not having seen a medical doctor for HIV care in the past three months, (2) not having a forthcoming scheduled appointment with an HIV provider, or (3) not currently taking HIV medications. It is possible that even though people were not deemed to currently be in HIV care by this definition, they may have had prior HIV care, a prior history of taking HIV medications, and had undetectable HIV viral load upon study entry. Because we did not find enough HIV positive participants in our “seek and test” phase, we supplemented HIV positive participants ($n = 19$) for the intervention study through referral from the local county jail HIV coordinator. A total of nineteen participants were enrolled in PBO between November 2011 and August 2013, of which ten were recruited through the targeted sampling effort and nine were from the supplemental referrals from the jail (Fig. 1). Among the people who were already in HIV care, 31 agreed to participate in the comparison group, including nineteen from the targeted sample and 12 from the supplemental referrals from the jail. Serum samples were immediately drawn from all 50 study participants for HIV viral load assessments. All study participants were asked to

return to the study field office every 3 months to have their blood drawn for HIV viral load assessments and to complete a brief follow-up survey that was conducted by an interviewer. These quarterly visits occurred until the formal end of the study in December 2014. Two comparison participants never returned for a follow-up visit and were dropped from this analysis, for a total sample of 19 intervention and 29 comparison participants who completed a total of 283 visits. Out of 48 study participants, 40 (83%) had at least 4 follow-up visits. Because the follow-up visits were censored in December, 2014, the number of feasible quarterly visits ranged from 5 to 13. The intervention group had a slightly higher mean (mean = 6.7 visits in intervention group and 5.4 visits in comparison group), but the same median (median = 6 for both groups) number of quarterly follow-up visits as the comparison group. The intervention and comparison groups had statistically similar ($p > 0.10$) demographic characteristics at baseline.

To assess HIV viral load, we used the Abbott RealTime HIV-1 Viral Load assay run on the m2000 system. This is an *in vitro* reverse transcription-polymerase chain reaction assay for the quantitation of Human Immunodeficiency Virus type 1 (HIV-1) in human plasma from HIV-1 infected individuals over the range of 40 to 10,000,000 copies/mL. The samples were thawed at room temperature, vortexed to homogenize the sample, and 1 mL was transferred to 4 mL self-standing Simport tubes to be loaded on the m2000 system. The results of which were then recorded, analyzed, and reported in copies/mL.

All study procedures were reviewed and approved by a federally accredited Institutional Review Board. Participants received \$20 remuneration at baseline and at every quarterly visit for their contribution to the research.

Project Bridge Oakland

The Project Bridge Oakland (PBO) intervention has been described in detail elsewhere [32, 33]. PBO is a strengths-based case management (SBCM) intervention for people who are HIV positive, adapted from Project Bridge in Providence, Rhode Island [34–36]. It was designed to facilitate retaining people in HIV care as they cycle in and out of the criminal justice system and to prevent HIV treatment gaps that may have deleterious effects upon health. SBCM interventions are based on the principle that it is best for case managers to build upon peoples' existing strengths [37, 38]. It assumes that people generally have a set of internal coping mechanisms that can be employed in order to solve whatever critical problems they face.

PBO participants received intensive case management provided by a master's level clinical social worker working in partnership with an HIV physician. The intervention was in place for the duration of the study, from enrollment to

December 2014. Participants were not paid for their participation in the intervention. Both the social worker and the HIV physician had a decade of experience working with this study population. They met with each other at a weekly case conference to strategize about each participants' clinical and social needs, such as generating medical documentation for eligibility in social service programs. The social worker kept clinical notes from each interaction with participants. In weekly meetings, a social work clinical supervisor reviewed these notes and co-signed them.

The amount of time the social worker spent with participants varied widely depending on their social and clinical needs and their living situation at any given time. This could range from daily meetings during times of intense activity to biweekly check-ins when participants were relatively stable. When participants fell out of contact, the social worker conducted outreach to them in homeless encampments, parks, and single room occupancy hotels. She also routinely accompanied them to medical, social service, and other appointments.

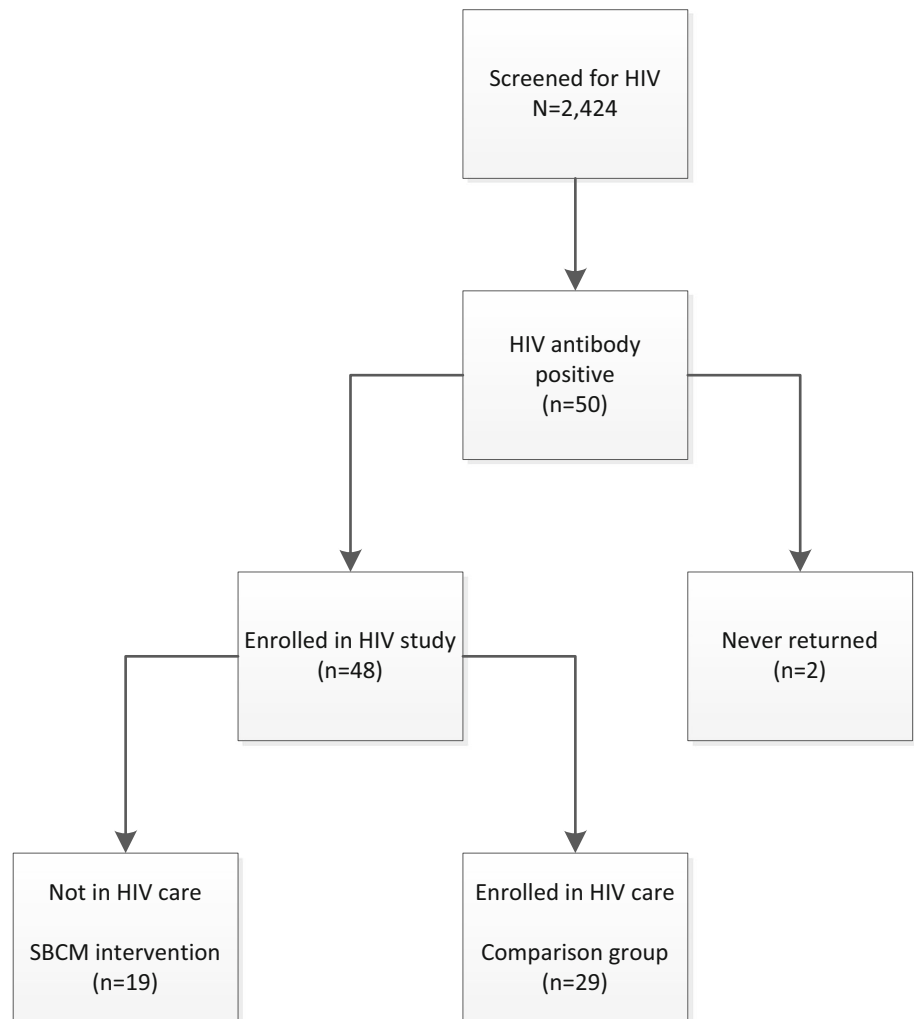
An important component of PBO was the social worker's role as a link between jail and community settings. At the onset of the intervention, she obtained signed release of information authorizations from each participant to contact the jail about HIV treatment should she learn that the participant was incarcerated, as well as to visit participants in jail. This enabled her to advocate for their access to HIV treatment while incarcerated and assist in coordinating strategies for continuity of HIV care upon release into the community. Participants frequently came directly to her field office upon exiting jail.

The comparison group were, by definition, already enrolled in HIV care. They did not receive any supplemental intervention or patient care from the study. After enrollment in the follow-up study, they only participated in the same follow-up data collection procedures as the PBO intervention participants, which included blood draw and follow-up interviews.

Measures

There were two main outcome variables in this analysis, both of which were measures of HIV viral load. First, we used a binary variable that denoted detectable or undetectable HIV viral load, with a viral load cut-point of <200 copies/mL, per HIV guidelines [39]. Second, we used a continuous variable that captures log₁₀ HIV viral load. Participants' viral load were assessed at baseline and each follow-up appointment through blood draw and HIV viral load testing. The primary explanatory variable was intervention group, which was a binary variable.

To reduce the potential intervention effect associated with having quarterly follow-up visits, we only asked a few

Fig. 1 Study flow chart

survey questions during those visits. We asked about criminal justice and unstable housing during the prior three-month period. We hypothesized that these two variables might be associated with both the intervention and the HIV viral load outcomes because they can disrupt the ability to continue taking medications. As such, we included two covariates that were assessed during the quarterly follow-up visits in our analyses: jail in past 3 months and unstable housing (having spent any time living on streets, parks, alleys or shelter at any point during the period) in past 3 months, both of which were binary yes/no variables.

Baseline characteristics that we asked about include self-identified gender (male, female, male to female transgender, female to male transgender, other); race/ethnicity (defined as African American, Caucasian, Latino/a, or Mixed Race/Other); age in years (18–30, 31–40, 41–50, and over 50); homeless; jail in past 12 months, and having ever injected drugs.

Statistical Analysis

We hypothesized that in this pilot intervention study, PBO participants would have higher odds of achieving HIV viral suppression over time than comparison participants. To assess this, we first conducted descriptive statistical analyses to learn about the distribution of the variables, including frequencies, median and interquartile range. Then we assessed whether the intervention group and comparison group had similar prevalence of the main demographic baseline variables. This includes using Chi square statistics to assess whether any observed differences were statistically significantly associated with intervention group, using an a priori p value cut-off of 0.10. The reason for choosing $p < 0.10$ a priori as the cut-off point for all analyses is the modest sample size ($n = 19$ in the PBO intervention group and $n = 29$ in the comparison group). Any baseline variables with statistically significant differ-

Table 1 Baseline demographic characteristics of study participants by intervention group (N = 48)

Demographic characteristic at baseline	Intervention (n = 19) (%)	Comparison (n = 29) (%)	Total (N = 48) (%)	Fisher's p value
Sex				
Cis-male	68	59	63	
Cis-female	21	31	27	
Transgendered male-to-female	11	10	10	0.82
Race/ethnicity				
African American/black	79	97	90	
European American/white	5	3	4	
Latino/a	5	0	2	
Other race/ethnicity	11	0	4	0.12
Age at baseline				
18–30 years	5	7	6	
31–40 years	32	7	17	
41–50 years	42	41	42	
Over 50 years	21	45	35	0.11
Homeless	74	62	67	0.54
Jail in past 12 months	63	41	50	0.24
Ever injected illicit drugs in past 6 months	21	21	21	1.00

Table 2 HIV viral load outcomes by intervention group and baseline vs last follow-up

Group and outcome variable	Baseline	Last follow-up	p value
Intervention group: undetectable HIV viral load	32%	74%	0.008
Comparison group: undetectable HIV viral load	45%	34%	0.36
Intervention group: median log HIV viral load	2.4	0	0.02
Comparison group: median log HIV viral load	1.8	2.2	0.43

ences between the intervention groups would be included as covariates in any multivariable analyses. Next, we calculated the prevalence of the undetectable viral load variable and median of the log₁₀ viral load outcome variables by intervention group, and conducted Chi square and t-test analyses to assess their statistical significance, with the a priori p-value cut-off of 0.10. We calculated these for the baseline assessment and the final follow-up assessment that was available for each participant. Finally, we tested the main hypothesis using GEE models with a binomial distribution and a logit link and an exchangeable correlation structure compared odds of undetectable viral load between the PBO intervention and the comparison groups over time. We utilized generalized estimating equation (GEE) models with a normal distribution and an identity link and an exchangeable correlation structure to compare changes in viral load (log₁₀-transformed) between the PBO intervention and the comparison groups over time. All GEE models included main effects for intervention condition and linear trend over time as well as an interaction between these terms to capture differences in change over time between intervention groups. We then added the two time-dependent covariates (jail and unstable housing during the

past 3 months as assessed during the quarterly follow-up visits). Again, we used an a priori p-value cut-off of 0.10 to determine statistical significance due to the small sample size and this being a pilot study. All analyses were conducted using SAS Version 9.4.

Results

The overall sample was a quarter cis-female, ten percent transgender male-to-female, predominantly African American and over 40 years old, and two-thirds homeless (Table 1). Half the sample had been in jail in the past year and nearly a quarter had ever injected illicit drugs. Participants reported having lived on the streets, in parks, or in temporary shelters at some point during 39% of their quarterly assessment periods. They reported having been in jail during 22% of their quarterly assessment periods. None reported being in prison during the study.

Our main outcome is HIV viral load, operationalized both as the binary variable undetectable/detectable and as the continuous variable log₁₀ viral load. At baseline, 32% of the intervention group and 45% of the comparison group

had undetectable viral load ($p = 0.36$; Table 2). At final follow-up visit, intervention participants were significantly more likely to have undetectable HIV viral load than comparison participants (74% vs. 34%, respectively; $p = 0.008$). The median log 10 viral load was also statistically similar at baseline among intervention and comparison participants (median 2.4 and 1.8, respectively; $p = 0.43$). And intervention participants had lower log viral load at their last follow-up visit than comparison participants (median: 0 vs. 2.2, respectively; $p = 0.02$).

In GEE repeated measures analysis, PBO intervention participants had a higher odds of achieving undetectable viral load over time than comparison participants (Intervention group: estimate = -0.3662 , standard error = 0.4884 , 95% confidence interval = -1.3235 , 0.5911 ; Days since baseline: estimate = -0.0005 , standard error = 0.0004 , 95% confidence interval = -0.0013 , 0.0003 ; Interaction between intervention group and days since baseline: estimate = 0.0016 , standard error = 0.0007 , 95% confidence interval = 0.0001 , 0.0030). The longer PBO participants were in the intervention, the higher the odds that their HIV viral load was undetectable. We also found a statistically significant relationship between intervention group and the continuous log 10 viral load outcome variable over time (Interaction between intervention group and days since baseline: estimate = -0.0013 , standard error = 0.0007 , 95% confidence interval = -0.0027 , -0.0000).

Adding the time-dependent quarterly follow-up visit jail and unstable housing variables to the multivariable GEE equation did not significantly change the main association of intervention group with the undetectable viral load outcome. Neither variable was statistically significantly associated with the outcome ($p > 0.10$). However, adding these time-dependent follow-up variables to the continuous log 10 viral load outcome GEE analysis ended up changing the main effect such that it was no longer statistically significant ($p = 0.24$). In that model, the time-dependent jail variable was independently statistically negatively associated with the log HIV viral load outcome ($p = 0.004$).

Discussion

In this pilot study, we found that people who reported not being in HIV care at baseline and who were subsequently enrolled in the PBO intervention were significantly more likely to have their HIV viral load become undetectable than those who met criteria for already being in HIV care at baseline. Within our sample, the PBO intervention appears to have helped this highly vulnerable group decrease their HIV viral load over time. Prior research has found that SBCM interventions are successful at linking people to HIV care [26–28]. Our pilot study is

the first, of which we are aware, to find that these interventions may also help people reduce viral load. It points to the importance of coordination between community and jail-based HIV providers [22]. Future studies using novel implementation science methods including stepped wedge designs [40] may help to establish generalizability of the findings of this study while ensuring that all of the participants have an opportunity to benefit from the intervention.

We found that if we controlled for jail stays during the study follow-up period, the effect of PBO on log HIV viral load outcome reduced to a non-statistically significant level. Log viral load outcomes were better during periods when participants reported some time in jail, compared to periods when they were not in jail, regardless of PBO participation. This is in the context of a jail that provided HIV care and an intervention that had a social worker engage HIV clinicians at the jail when their patients were jailed. However, incarceration is neither an effective nor ethical solution to the need for a lifetime of HIV care. The PBO model, by contrast, addressed the challenges experienced by this vulnerable population in their everyday lives, increasing the potential for sustained participation in care. We found that unstable housing was not a contributing factor to either HIV viral load outcome once the effects of PBO were considered. This may be a function of PBO being effective at reducing HIV care barriers specifically related to homelessness.

The findings in this study need to be considered in light of potential limitations. Participants were not randomized to PBO and comparison groups. While we had intended for the study to be randomized, we did not find sufficient numbers of HIV positive participants who were not already in care ($n = 19$) to conduct such a study. We did not find any statistically significant differences in the prevalence of demographic characteristics between the intervention and comparison groups, but there are potential unknown selection biases that may have influenced group membership. HIV viral load was statistically similar between the two groups at baseline. There are many potential reasons for why nearly one-third of the participants who had reported they were not in HIV care had undetectable viral load upon study entry, including prior HIV care and medication adherence or misreporting. In Iroh et al.'s systematic review, they found that a similar percentage of incarcerated people (28%) had an undetectable viral load upon becoming incarcerated [22].

The second important limitation is that this study had a very small sample size. While we screened over 2000 people who use drugs for HIV, very few were HIV antibody positive, and even fewer were not already in HIV care. While this is excellent for community health and speaks to the strengths of Alameda County, California, in

providing HIV prevention, testing, and treatment services, the small sample size is nonetheless a study limitation. We set our cut-off value for statistical significance ($p < 0.10$) prior to conducting our analysis. Future evaluations of PBO should include more participants and multiple sites. This would also enable us to learn more about the generalizability of the findings beyond our intervention in Oakland. Third, there was a sizeable amount of attrition. While 83% of participants had at least four follow-up visits, a minority (13/48) had 8 or more quarterly visits. Given the small sample size, it is hard to assess whether there was statistically significant differential attrition based upon important variables. The intervention and comparison groups had similar mean and median number of follow-up visits. Lastly, with the exception of explanatory (intervention group) and outcome (HIV viral load) variables, this study relied on self-reported data related to behaviors. These data can be subject to recall or social desirability biases.

Despite the potential biases and limitations of our study design, this small evaluation study showed that PBO has promise for improving HIV viral load for a highly vulnerable population with few resources. Whereas prior studies have found that SBCM is effective for linking people to HIV care, [26–28] our findings suggest that it may also help them reduce HIV load, even in the context of cycling between correctional and community settings. Social workers who are working with HIV patients should consider building bridges with local correctional health practitioners. These preliminary results also indicate the importance of physicians and social workers working in tandem with their most challenging HIV patients.

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Compliance and Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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