



Peer Support and the HIV Continuum of Care: Results from a Multi-Site Randomized Clinical Trial in Three Urban Clinics in the United States

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Abstract

Racial/ethnic minorities living with HIV and behavioral health co-morbidities are more likely to be disengaged from HIV primary care. Peer programs have been effective in HIV outreach and prevention but effectiveness of such programs for retention in care and viral suppression is understudied. Subjects ($n = 348$) were randomized in equal allocation to a peer navigation and education intervention versus standard clinical care at three urban clinics in the United States. The intervention group received seven structured interventions plus weekly contact to address medical and social needs. Primary outcomes included time-to-first 4-month gap in HIV care and viral suppression up to 12 months of follow-up. Intention-to-treat analysis showed no difference between groups on 4-month gap in HIV primary care, but subgroup analysis showed a suggestive effect of the peer intervention in reducing gaps in care among stably housed subjects. Fully compliant subjects in the peer intervention experienced significantly fewer 4-month gaps in HIV primary care ($p < 0.0001$). Those in the peer group who had more clinical face-to-face encounters in the first 3 months were also significantly more likely to have better retention in care ($p = 0.04$). There were no significant differences between any study subgroups in viral suppression at 12 months. Peer interventions may improve retention in primary care among subgroups of people living with HIV from racial/ethnic minority communities, although such improved retention may not increase viral load suppression. Attending and completing structured educational sessions along with early, intensive contact with peers could improve retention in HIV primary care for patients. Future peer programs should consider training on housing referral systems to help increase retention for patients who are not stably housed. clinicaltrials.gov registration number: NCT01616940.

Keywords Patient engagement · HIV primary care · Patient navigation · Intervention with peers · Minority health · Randomized clinical trial

We dedicate this manuscript to the memory of Tammy Gilliam, whose commitment and devotion to her patients and her family was an inspiration to all.

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Introduction

With the advent of the HIV Care Continuum [1] and the 2015 update of the National HIV/AIDS Strategy [2] a concerted effort has been initiated to increase a targeted focus on populations who are not linked or consistently engaged in HIV primary care that would ultimately lead to viral suppression. Recent studies have shown that early use of antiretroviral treatment in PLWHA (Person(s) Living with HIV/AIDS) and sero-discordant partners may reduce the transmission of HIV by as much as 75% thus increasing the prospect that the HIV epidemic could be stopped [3, 4]. These advances heighten the need for programs to develop innovative and effective ways to successfully link and retain newly diagnosed patients in high quality HIV primary care

as well as re-engage and retain patients who have disengaged or are loosely linked to HIV primary care.

Past studies have found Blacks and Hispanics, particularly those with behavioral health co-morbidities such as mental illness and substance abuse and those with lower socio-economic status are more likely to be disengaged from HIV care and have poor adherence to treatment [5–9]. In an attempt to increase access to HIV primary care and treatment and maintain patient engagement in care, new strategies have been developed. There is recent evidence to support the use of “enhanced contact,” using a dedicated person to improve patient retention for HIV primary care in a randomized clinical trial [10].

An additional strategy is the incorporation of trained HIV positive peers in the HIV clinical team. The concept of using peers is one that has been studied in the United States and been found effective in some HIV outreach, education and prevention programs that used randomized clinical trial designs, but not in all studies [11–14]. Recent systematic reviews have found that peer interventions may be a promising approach to linking and retaining patients in care but studies are limited and have yielded mixed results on the impact on adherence to treatment and viral suppression [15–17]. The implementation of peer-based interventions has proven effective in other health conditions working with low income populations. Peers providing coaching tasks and support have been found effective in improving diabetes care by improving glycemic index [18]. In addition, the Veteran’s Administration has hired a number of peers in the recent years to assist in providing support to patients with serious mental illness receiving intensive case management services. The goal of the peer support program is to assist patients in becoming more activated in their treatment. The results thus far are modest with no significant differences with patients being activated in their treatment between those who received peer support and the standard of care [19, 20].

In relation to HIV care, presently there is limited experience and evidence to support the peer role as part of the clinical team in engaging and retaining patients in HIV primary care. Some studies have shown promising results but very few to-date used randomized clinical trials in order to test their efficacy [17]. These models of care incorporate trained peers into the clinical team to educate and assist patients who have challenges accessing and consistently engaging in HIV primary care.

Previous studies have found that the main role of peers in the HIV care team, compared to other members of the HIV team such as case managers or social workers, has been in support that can be classified into four main domains: (1) emotional, (2) informational, (3) instrumental and (4) affiliation support. Within each of the supportive roles there are also defined tasks carried out by peers [21] which may

include education about HIV, the virus life cycle, and HIV care and treatment; navigating the service system to obtain necessary medical and supportive care; and emotional support and coaching/mentoring to manage life with HIV. Incorporating peers into the clinical team allows for optimal information exchange between clinicians, case managers and the peers to best meet and support the needs of the patients [22].

Limited research in the United States has examined the effect of peer support workers on clinical outcomes and retaining patients in care. Previous studies of both peer and non-peer outreach workers found that a minimum of weekly contacts for three months and appointment accompaniment resulted in improved engagement in care at 6 and 12 months [23]. However, these peer and non-peer staff were not necessarily part of a medical care team. The purpose of this report is to evaluate the impact of an enhanced peer intervention in a randomized clinical trial on engaging and retaining people of color living with HIV/AIDS in care and treatment and achieving viral suppression.

Methods

The study was conducted at three clinical sites located in Miami, FL (Care Resource); Brooklyn, NY (The Brooklyn Hospital Program for AIDS Treatment & Health Center); and San Juan, Puerto Rico (Puerto Rico Community Network for Clinical Research on AIDS) and funded through the Minority AIDS Initiative of the Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau as a Special Project of National Significance (HRSA/SPNS/SMAIF). These three sites were selected based on the following criteria: each was funded as a Ryan White Part C clinic; located in HRSA-identified priority geographic regions with a high HIV prevalence; and served a predominantly racial-ethnic minority population. Boston University School of Public Health served at the multi-site evaluation center and was responsible for all aspects of study design, management and analysis.

Individuals were considered eligible for this study if they met the following HRSA/SPNS/SMAIF determined program population criteria for this specific project: (1) HIV-positive, (2) 18 years of age or older, (3) identified as belonging to one or more of the following categories: American Indian or Alaskan Native, Asian, Black or African-American, Hispanic or Latino, native Hawaiian or other Pacific Islander, (4) had at least one of the following risk factors: (a) was out of medical care for 4 months or more, (b) was a new patient to the clinic and indicated a need for substance use, mental health or housing services or (c) newly diagnosed with HIV in the past 6 months and indicated a need for substance use, mental health or housing services. To identify eligible participants for the study, sites employed multiple

recruitment strategies including: linking with internal or external HIV counseling and testing departments or agencies and reviewing electronic medical records and clinical appointment record systems to identify patients who had been out of care for 4 months or more. Program staff contacted eligible participants to discuss the study intervention. Subjects were enrolled between May 2012 and March 2013 and followed for 12 months. Data were collected between May 2012 and March 2014 with intervention conducted for up to 12 months.

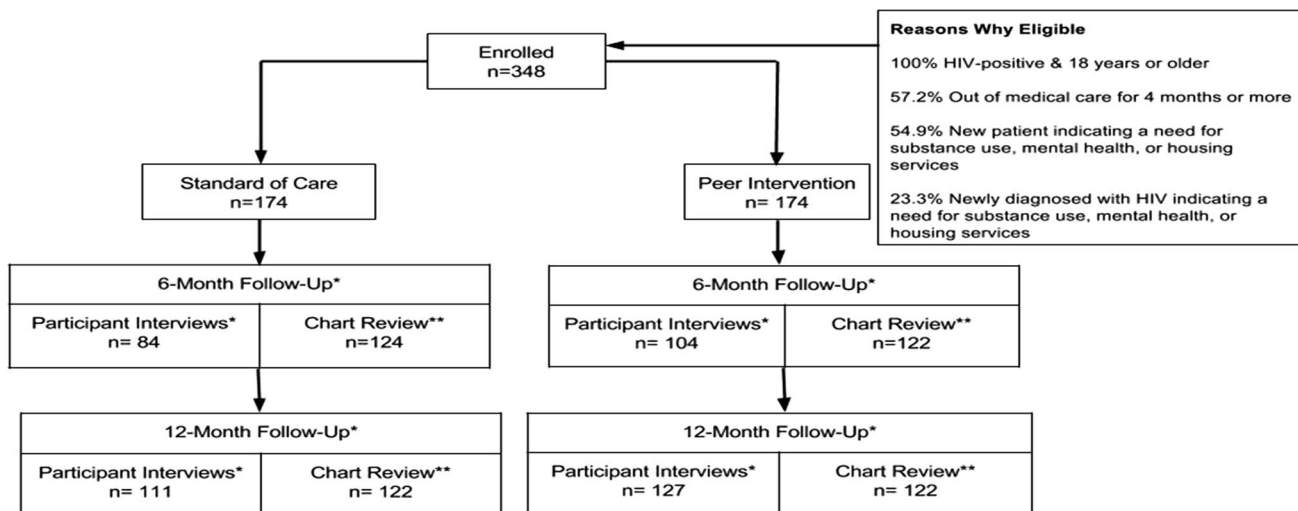
We randomized patients to each of the study groups using a parallel groups design, i.e., once randomized with no crossover to the other group: enhanced peer intervention or standard of HIV care (the customary care provided to all patients at each of the clinics inclusive of medical care, case management and support services). The protocol of the study was approved by the Institutional Review Boards of the study sites and the Boston University Medical Campus. The study was registered in *clinicaltrials.gov*. A Certificate of Confidentiality from the United States Department of Health and Human Services was obtained and notification of this was included during the consent process for each subject. Figure 1 shows the steps in patient enrollment.

Description of the Peer Intervention

The intervention was based on the social support framework that peers, as people living with HIV, could provide a unique supportive role on the health care team that would improve retention in care and lead to viral suppression. Specifically in this study, the peer role and accompanying tasks addressed

four domains: (1) informational support communicating information about HIV its treatment and healthy living; (2) instrumental support assisting with reducing barriers to care and obtain needed services through knowledge of resources, making appointment reminders and accompaniment to visits; (3) emotional support by providing active listening and coaching to manage the illness through sharing personal stories and experience; and (4) affiliational support connecting the patient to social networks and providing the person with a community to keep them engaged in care [21]. Table 1 shows the content and structure of the 7 sessions in this intervention.

Subjects assigned to the intervention group received standard HIV care plus enhanced peer support. Peer support included 7 one-on-one educational sessions for 60 min every 1–3 weeks on specific topics that enhanced HIV care and treatment. During the same period, the peer also conducted weekly check-ins by phone or in person which ranged from 30 to 60 min or every 2 weeks for up to 4 months. These interactions focused mainly on relationship building. In addition, peers were trained to provide reminders of scheduled appointments, and to debrief on medical visits and support for treatment. Following completion of the sessions, patients continued to receive biweekly contact from the peer for reminders about any upcoming medical or other appointments, to discuss treatment adherence, to obtain additional supportive services, and to check in for support to reduce isolation. While peers worked in a supportive role with patients and the case managers, they did not conduct the work of case managers. The case managers continued to work with patients to conduct needs assessments, identify



* First section of follow-up interviews were interviewer-administered; the remaining sections were self-administered by subject using Audio Computer-Assisted Self-Interviewing (ACASI) system

**Chart review sample sizes only include subjects for whom viral load data was available.

Fig. 1 Enrollment, randomization, and follow-up

Table 1 Content of peer education modules

Session 1—Introduction and Assessment	The purpose of this introductory session was to start to develop the peer-patient relationship. A standardized set of questions was used by peers to learn about the patient's history of HIV status, engagement in and barriers to care, current medications, social support access, housing status, and general concerns
Session 2—HIV Transmission and the Viral Life Cycle	This "HIV 101" session was used to review the stages of HIV infection (e.g. acute, asymptomatic, AIDS), the steps of the HIV viral life cycle at the cellular level (e.g. attachment, fusion, reverse transcription), and the multiple routes of transmission (e.g. anal sex, vaginal sex, intravenous drug use)
Session 3—Effective Communication and Self- Advocacy (on-going)	This session provided tools and tips for patients to prepare for visits and communicate with medical providers, and informed patients of their rights and responsibilities
Session 4—Understanding Lab Values	This session reviewed common monitoring lab tests for PLWH (e.g. CD4 count, viral load count) and explained the respective results
Session 5—HIV Medications	This session provided a general overview of the different kinds of HIV medications that are available (e.g. entry inhibitors, integrase inhibitors), how they work, and where they fit into the HIV viral life cycle
Session 6—Drug Resistance and Adherence; Understanding and Managing Side Effects	This session began with an assessment of medication adherence, barriers to adherence, and side effects experienced. It also included discussions around medication resistance and planning for how to reduce barriers (e.g. side-effects) to treatment adherence
Session 7—Disclosure and Stigma	This session allowed the patient to discuss issues around stigma and disclosure that they have experienced and provides them with tips for decision-making around disclosure (e.g. who to tell, when to disclose, where to have these conversation, etc.)
Session 8—Harm and Risk Reduction	This session focused on prevention with regards to sexual health and substance use and describes the risk hierarchy of HIV transmission for PLWH. The patient was encouraged to share as much as he or she felt comfortable with regards to his or her own risk behaviors, and was offered harm reduction tips by the peer

and make appropriate referrals and assist patients in completing paper work and applying for benefits and services, such as housing. The time frame for the intervention was a minimum of 2 months with a maximum of 12 months. Prior to start of the intervention, each site hired two peers to implement the intervention. The peer role was specifically designed to enhance the existing standard-of-care in the clinic. Peers documented their activities with clients on a weekly or daily basis.

Each site recruited and hired peers from their existing patient population. Peers were HIV positive, engaged in medical care, and comfortable sharing their life experiences and HIV status with others to build a supportive relationship. In addition to being HIV-positive, peers may also have shared other identities based on gender, sexual orientation or history of substance use consistent with the patient populations unique to the sites. All peers represented the same racial ethnic minority communities as the patients served.

Contracted expert HIV peer trainers conducted a 4.5-day standardized training for peers at each of the three sites. A half-day training was provided to all members of the HIV care team with the peers to clarify peer roles and clearly delineate responsibilities between peers and other members

of the care team. At each site peers were hired as employees and provided standard training on HIPAA and confidentiality regulations. As employees, the peers were provided access to medical and case management records and were trained to document their interactions as other members of the clinical team. Supervision was provided to peers by a designated staff at each of the study sites. Supervisors received a standardized one-day training to support peers in their role as members of the HIV care team, and strategies for managing patients with multiple needs and co-morbidities. Monthly calls were conducted with all peers across the sites to provide additional training and support with client cases. Each site had clinical supervision in individual and/or group settings on a monthly basis. An in-depth programmatic description and implementation manual as well as all training curricula for this project can be found at <http://cahp.org/project/minority-aids-initiative-retention-and-re-engagement-in-hiv-care-project/>.

Subjects assigned to the standard-of-care groups were re-connected or assigned to a medical case manager and provided an appointment with an HIV clinician in accordance with the standard procedures of the clinic site.

Longitudinal Study Design and Measures

Data collection methods consisted of three components: (1) participant survey (2) medical and case management chart reviews, and (3) peer encounter forms. Survey data, including participant demographics, service utilization, quality of life, self-efficacy and HIV knowledge, were collected via audio computer-assisted self-interview software (ACASI) and interviewer administered web-based survey at baseline, 6 and 12 months in English and Spanish as preferred by the study subject with real-time web-based link to the main study database at the Boston University School of Public Health Data Coordinating Center (DCC). Medical chart reviews were completed at 6 and 12 months post-randomization by clinical personnel at each site trained to a common data collection protocol and recorded on paper Tel-eForms formatted for scanning and secure electronic transfer to the (DCC). Medical case management visits were collected monthly during the lifespan of the intervention. Peer encounter forms were completed by peers to document their activities related to the study clients, including all completed education sessions, and other services provided to clients. Type (face-to-face, phone, email) and duration of contact were also collected. Annual site visits were conducted by the research staff of the evaluation center at the Boston University School of Public Health to verify data from all sources (surveys, chart reviews and peer encounter forms) and were in support of risk-based monitoring approaches using regular and systematic remote data review methods consistent with current standards for clinical trials.

Our primary outcomes were retention in care and viral suppression at 12 months (laboratory results of less than to 200 copies/mL). Retention in care was measured as time-to-first gap in care of 4 months or longer as well as using a binary variable indicating any such gap in a 12-month period. Viral suppression was examined when available for each subject as a time-dependent binary outcome (having an undetectable viral load) at baseline, 6 months and 12 months. Other secondary, longitudinal outcomes were considered to be intermediate to retention in HIV primary care and viral suppression. These included changes in *HIV knowledge* measured by the Balfour scale a validated score that examines HIV care and treatment knowledge among PLWHA [24]; *Self-efficacy* was measured using two scales from the validated Stanford Patient Education Research Center's Chronic Disease Self-Efficacy Scales [25]. In particular, we used the "Getting Information About Disease" one-item scale that asked about finding resources in the community about HIV, and the "Communicate with Physician Scale" which consisted of 3 items that assessed ability to communicate with one's health care providers about HIV. These scales were selected from all scales (there are a total of 10) because we hypothesized that these would be

the areas in which a peer intervention could affect change. We also used the SF-8 validated scale to measure *physical and mental health quality of life* [26].

Statistical Analysis

Prior to formally testing each of our primary study aims, we evaluated the success of our randomization by examining the balance of the distributions of salient patient characteristics between the peer and standard-of-care groups. In these analyses, we compared percentages with χ^2 tests of significance for categorical variables as well as means with two sample t-tests for continuous variables. In our primary analyses, we compared the groups on the time-to first 4-month gap in HIV primary care by generating Kaplan–Meier curves with statistical testing using a log-rank test. We verified the proportionality of hazards by incorporating a group-by-time interaction term in a Cox proportional hazards regression model comparing log(-log) plots for the two groups. We also compared the groups on any 4-month gap in HIV primary care using cross-tabulations and χ^2 tests. In order to compare the attainment of viral suppression among those with detectable values at baseline, we compared proportions between the study groups separately at 6 months and at 12 months of follow-up using cross-tabulations to generate counts and percentages with χ^2 tests of significance. Given that randomization does not preclude heterogeneity of intervention effects, we examined a limited number of salient baseline variables guided by theory and the literature as potential effect modifiers using stratified analyses and testing for interaction in our statistical models. We employed the intention-to-treat principle (i.e., all subjects once randomized are included in the analysis regardless of completion of the intervention) in all comparative analyses and applied an alpha level of 0.05 for all statistical tests. Statistical testing was also performed taking into account potential clustering by site by covariance adjustment in Cox regression and linear mixed models.

In addition to analyses employing intention-to-treat, we examined the effects of varied doses of the peer intervention as measured by the number of education sessions completed, with a potential maximum of 7 sessions per subject, as well as by the number of face-to-face clinical encounters by peers. We also performed these analyses both unadjusted and adjusted for the number of medical case management encounters per subject outside of the intervention. These adjusted analyses included Cox proportional hazards regression for time-to-4-month gap in HIV primary care, multiple logistic regression using generalized estimating equations (GEE) for viral suppression during the 6-to-13 month window of follow-up, and mixed linear models with covariance adjustment for longitudinal measures HIV knowledge, self-efficacy, and health-related quality of life. In sensitivity analyses, we employed multiple imputation to generate 20

imputed data sets to compare to the results of the complete-case analyses in our analyses of viral suppression at 6 and 12 months and in our GEE and mixed linear models. All analyses were performed in SAS version 9.4.

Results

Effectiveness of Randomization

As seen in Table 2, we achieved balance in the distributions of all salient baseline characteristics as a result of the randomization between the Peer and Standard-of-Care groups that was conducted at each site. Although these differences

were uniformly not statistically significant, we did observe that subjects who were randomized to the Peer group were slightly more likely to be currently unemployed or homeless at the time of the baseline interview.

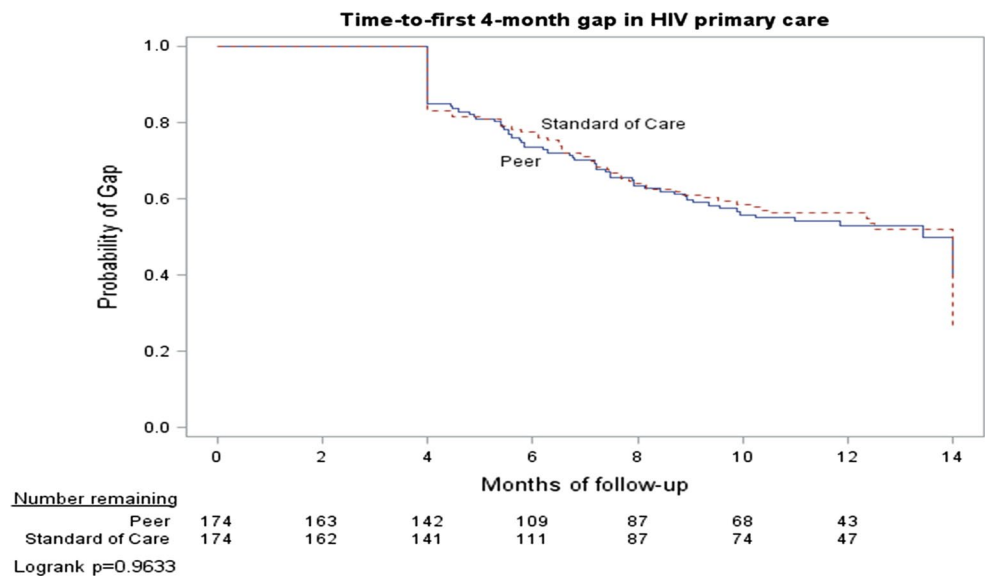
Intent-to-Treat Analyses of Outcomes

We compared the time-to-first 4-month gap in HIV primary care during 13 months of follow-up using Kaplan–Meier survival curves with log-rank testing. As seen in Fig. 2, there was no substantial or statistically significant difference between the Peer and Standard-of-Care groups in the time to such a gap ($\chi^2(1) = 0.002$, $p = 0.96$). The proportionality of hazards assumption between groups was met in

Table 2 Baseline characteristics for all 3 sites by study arm ($N = 348$)

	Peer-enhanced ($N = 174$)	Standard-of-care ($N = 174$)	p value χ
Mean age (SD)	39.1 (11.5)	40.5 (10.9)	0.25 ($t(346) = 1.15$)
Race/ethnicity			
African-American	52%	47%	0.56
Hispanic	44	50	$\chi^2(2) = 1.17$
Other	4	3	
Gender			
Male	73%	78%	0.31
Female	26	22	Fisher's exact test
Transgender	1	0	
Sexual orientation			
Heterosexual	55%	47%	0.15
Homosexual	34	45	$\chi^2(2) = 3.79$
Bisexual	11	8	
Primary language			
English	64%	66%	0.82
			Fisher's exact test
Mean years of education (SD)	11.5 (3.0)	12.0 (3.0)	0.11 ($t(346) = 1.62$)
Currently homeless	24%	16%	0.06 $\chi^2(1) = 3.61$
Unstably housed in past 6 months	56%	53%	0.52 $\chi^2(1) = 0.42$
Unemployed	82%	74%	0.06 $\chi^2(1) = 3.65$
Medicaid	57%	51%	0.24 $\chi^2(1) = 1.41$
Years since first HIV positive, median (25th, 75th percentiles)	6.2 (1.0, 15.6)	6.9 (2.1, 14.1)	0.88 Wilcoxon rank sum test, t approx.
Undetectable viral load (within 30 days of enrollment)	48% ($n = 112$)	47% ($n = 109$)	0.94 $\chi^2(1) = 0.005$
Out-of-care for 4 months or more	56%	58%	0.75 $\chi^2(1) = 0.11$
New to clinic	56%	54%	0.75 $\chi^2(1) = 0.10$
Newly diagnosed	21%	26%	0.25 $\chi^2(1) = 1.30$
Currently taking medication for HIV	49%	49%	0.91 $\chi^2(1) = 0.01$
Currently taking medication for depression	17%	20%	0.56 $\chi^2(1) = 0.34$
In alcohol or drug treatment in past 6 months	16%	12%	0.28 $\chi^2(1) = 1.16$
Mean HIV knowledge score (SD)	71.8 (17.8; $n = 163$)	72.9 (19.3; $n = 166$)	0.57 ($t(327) = 0.57$)
Mean SF-8 mental composite score (SD)	40.7 (11.4)	41.8 (10.3)	0.33 ($t(326) = 0.97$)
Mean SF-8 physical composite score (SD)	43.8 (8.5)	44.6 (8.6)	0.43 ($t(326) = 0.80$)
Mean self-efficacy score (SD)	36.1 (6.0)	36.5 (5.2)	0.53 ($t(327) = 0.63$)

Fig. 2 Kaplan-Meier curves for time-to first-4 month gap in HIV primary care by study group



these data and the differences were not altered by adjustment for study site in a simple Cox survival regression model. In addition to this analysis, there was no meaningful statistical difference between the standard-of-care and peer intervention group in the occurrence of any 4-month gap in HIV primary care (39% standard-of-care vs. 40% peers, $\chi^2(1) = 0.05$, $p = 0.83$).

Although effective randomization achieved balance between the Peer and Standard-of-Care groups on relevant baseline characteristics that eliminates the potential confounding effects of these variables, it does not preclude the presence of effect modification (interaction) by these variables on comparisons of outcomes between the study groups. To assess this potential interaction, we examined as potential effect modifiers a set of baseline variables that included gender, age in years (13–24, 25–49, and 50+), primary language (English, Spanish, Haitian Creole, or other), having been out-of-care for 4 months or more prior to the study, being a patient who was new to the clinic, being newly diagnosed with HIV within the 12 months prior to the study, having a detectable viral load at baseline, having a lifetime or current history of mental health or substance abuse problems, being unstably housed (in transitional housing, homelessness or expressed need for housing in past 6 months), and having ever been in jail in his or her lifetime. We found substantial differences only in the effect of the Peer intervention versus Standard-of-Care between those who were housed and those who were unstably housed (Cox regression interaction test, $\chi^2(1) = 5.52$, $p = 0.02$; Breslow-Day test of interaction for any 4-month gap, $\chi^2(1) = 6.00$, $p = 0.01$).

As seen in Fig. 3, subjects in the Peer group who were unstably housed at baseline were more likely, though not significantly, than those in the Standard-of-Care to

have had a 4-month gap in HIV primary care (log rank $\chi^2(1) = 2.80$, $p = 0.09$). In contrast (Fig. 3), among those who were stably housed at baseline, there was suggestive evidence for earlier 4-month gaps in HIV primary care in the Standard-of-Care group compared to subjects in the Peer group (log rank $\chi^2(1) = 3.36$, $p = 0.07$).

Viral Suppression at End of Follow-Up

In intention-to-treat analyses, we also examined differences in clinical outcome as determined by a subject having only undetectable viral load tests in two separate intervals of follow-up, baseline-to-6 months and greater than 6-months to 13 months (Table 3).

Between baseline and 6 months of follow-up, we found no difference between the Peer and Standard-of-Care groups ($\chi^2(1) = 0.02$, $p = 0.89$) in the proportion of subjects who were virally suppressed, with the proportion in each group of 52%. However, in the greater than 6 months-to-13-month interval, the proportion of subjects virally suppressed was significantly higher in the Standard-of-Care group than the Peer group ($\chi^2(1) = 4.31$, $p = 0.04$) where the proportions of subjects were 65% and 52% respectively. Notably, the proportion of subjects with missing viral load data was the same (approximately 30%) between the groups at both 6 and 12 months. Moreover, using multiple imputation for viral suppression at each of 6 and 12 months with homeless status and study site as predictors of missingness, the association of study group with outcome was similar in the imputed data sets when compared to the non-imputed data (results available upon request).

Kaplan-Meier analyses of time-to-first 4-month gap in HIV primary care by study group stratified by stable/unstable housing status at baseline (interaction $p=0.02$)

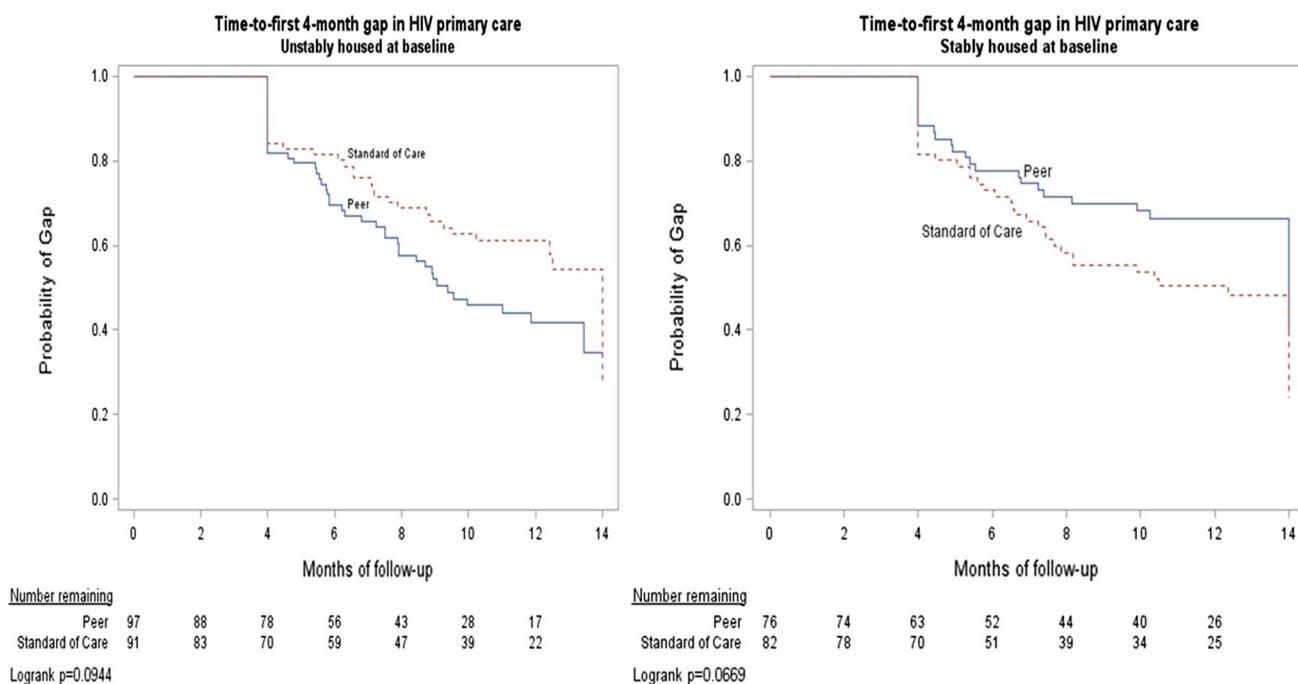


Fig. 3 Kaplan-Meier curves for time-to first-4 month gap in HIV primary care by study group for those unstably and stably housed at baseline

Table 3 Undetectable viral load in two follow-up windows by Peer versus standard-of-care

	Baseline to 6 months			Greater than 6 months to 12 months		
	Peer ($n = 122$)	Standard-of-care ($n = 124$)	p value	Peer ($n = 122$)	Standard-of-care ($n = 122$)	p value
No detectable viral load in window	52%	52%	0.89 $\chi^2(1) = 0.02$	52%	65%	0.04 $\chi^2(1) = 4.31$

As Treated Analysis by Level of Peer Education Sessions

Time to 4-Month Gap in Care

(a) Time-dependent level of peer education

As seen in Fig. 4, when examining the level of peer education sessions as a time-dependent, categorical independent variable with time-to-first 4-month gap in HIV primary care, we found a highly statistically significant difference between those who were randomized to the Peer intervention but had completed no educational sessions, those in the Peer group who had completed 1–6 educational sessions, and those in the Peer group who had completed all 7 educational sessions (log rank $\chi^2(2) = 36.47, p < 0.0001$). Based

on Kaplan–Meier estimates of the probability of a 4-month gap in care, those in the Peer group who completed all 7 sessions experienced substantially fewer 4-month gaps in care (0.00 by 6 months; 0.14 by 12 months) compared to those in the Peer group with no completed sessions (0.00 by 6 months; 0.84 by 12 months) and those in the Peer group who had completed 1–6 sessions (0.09 by 6 months; 0.55 by 12 months). In addition to examining the effect of education by peers on a 4-month gap in care, we also examined data collected on: (a) education sessions completed; and (b) clinical face-to-face encounters with peers for each patient restricted to the first 3 months of intervention prior to the occurrence of a gap. For education sessions completed within the first 3 months of intervention, in a Cox proportional hazards regression we found a statistically significant 18% reduction in the risk of a gap in care (hazard ratio = 0.82, 95% CI 0.72, 0.94, $p = 0.003$). Also, using

Fig. 4 Kaplan-Meier curves for time-to first-4 month gap in HIV primary care by level of peer education sessions completed

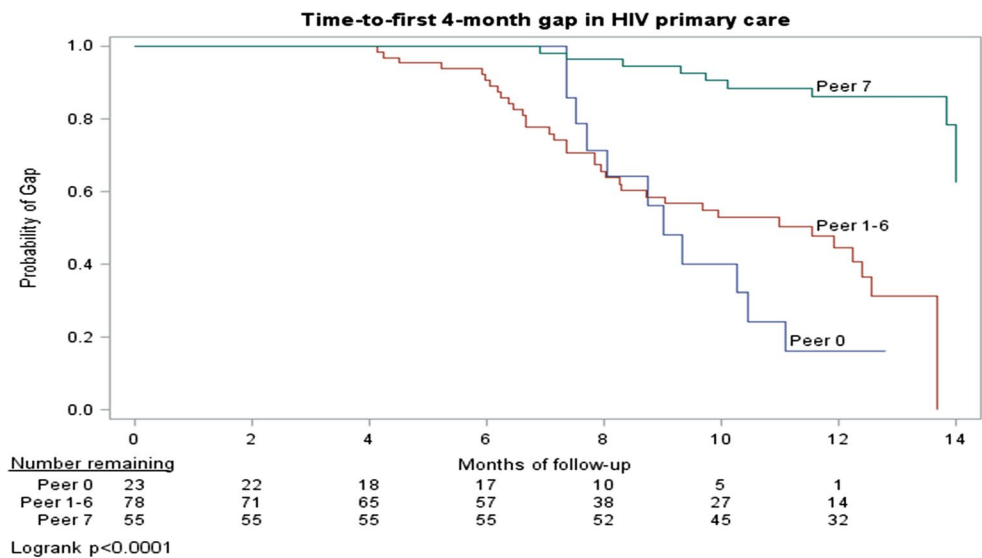


Table 4 Viral suppression in the 12 month study window by number of Peer education sessions completed prior to the date of laboratory testing

	12 month window			<i>p</i> value
	None (<i>n</i> = 25)	1–6 sessions (<i>n</i> = 72)	All 7 sessions (<i>n</i> = 23)	
Viral suppression in window	40%	54%	57%	0.41 $\chi^2(2) = 1.76$

Cox proportional hazards regression, we found a statistically significant 11% reduction in the risk of a gap in care per face-to-face encounter (hazard ratio = 0.89, 95% CI 0.80, 0.99, $p = 0.04$). These results were not meaningfully changed in effect size or statistical significance after controlling for the number of medical case management encounters at the clinic.

Viral Suppression During Follow-Up

Finally, we explored what effect, if any, dose had on viral suppression during the 12-month window (Table 4). In this analysis, dose was once again categorized into 3 groups based on the number of completed educational sessions as seen previously, however, the number of completed educational sessions were truncated at 6 months post randomization in order to avoid any overlap between our outcome of interest and our dose variable. Results showed there was no significant difference by dose category in the proportion of subjects with viral suppression at 12 months ($\chi^2(2) = 1.76$, $p = 0.41$). Fifty-seven percent (57%) of subjects who completed all 7 educational sessions by 6 months were virally

suppressed at 12 months, followed by 54% virally suppressed of subjects who completed 1–6 educational sessions by 6 months, and 40% virally suppressed of subjects who completed 0 educational sessions by 6 months. These results did not change after adjusting for the number of case management visits truncated at 6 months.

HIV Knowledge, Self-Efficacy, and Health-Related Quality of Life

There were no significant differences in changes in HIV knowledge or self-efficacy between the peer and standard-of-care groups and both groups experienced improvements over time (Table 5). Similar results were found for the health related quality of life as measured using the Mental Composite Score (MCS) and Physical Composite Score (PCS) from the SF-8. Both groups demonstrated improvements over time from baseline through 12 months with as much as a 2-to-3-unit increase in mean score for PCS and 1-to-2-unit increase in mean score for MCS. There were no significant differences, however, between the two groups in these levels of change over time. In analyses of the multiply imputed data sets noted above, we found no substantial differences with the results of our complete cases analyses.

Discussion

In this randomized clinical trial of a model of enhanced peer intervention compared to the standard-of-care at three clinical sites with hard-to-reach patients largely of ethnic minorities in the United States (Brooklyn, NY; Miami, FL; San Juan, Puerto Rico), we found in intention-to-treat analyses no evidence of a difference in retention in HIV primary care of viral load suppression between the Peer intervention

Table 5 HIV Knowledge, self-efficacy, health-related quality of life by study group over time

	Baseline		6 months		12 months		<i>p</i> value, group-by-time interaction ^a
	Mean (SD, <i>n</i>)		Peer (<i>n</i> = 104)		Standard-of-care (<i>n</i> = 84)		
	Peer (<i>n</i> = 174)	Standard-of-care (<i>n</i> = 174)	Standard-of-care (<i>n</i> = 166)	Peer (<i>n</i> = 166)	Standard-of-care (<i>n</i> = 163)	Peer (<i>n</i> = 163)	
HIV knowledge score	71.8 (17.87; <i>n</i> = 163)	73.0 (19.3; <i>n</i> = 166)	79.2 (12.5; <i>n</i> = 98)	78.6 (14.3; <i>n</i> = 83)	79.2 (14.2; <i>n</i> = 125)	79.4 (13.7; <i>n</i> = 110)	0.73 (F(2, 401) = 0.31)
Self efficacy score	36.1 (6.0; <i>n</i> = 163)	36.5 (5.2; <i>n</i> = 166)	37.0 (4.9; <i>n</i> = 103)	37.5 (5.2; <i>n</i> = 81)	38.1 (3.4; <i>n</i> = 124)	37.4 (5.2; <i>n</i> = 109)	0.37 (F(2399) = 0.99)
Mental Composite score (MCS), SF-8	40.7 (11.4; <i>n</i> = 165)	41.8 (10.3; <i>n</i> = 163)	40.7 (11.4; <i>n</i> = 165)	41.8 (10.3; <i>n</i> = 163)	44.2 (11.0; <i>n</i> = 123)	44.8 (9.0; <i>n</i> = 109)	0.92 (F(2542) = 0.09)
Physical composite score (PCS), SF-8	43.8 (8.5; <i>n</i> = 165)	44.6 (8.6; <i>n</i> = 163)	43.8 (8.5; <i>n</i> = 165)	44.6 (8.6; <i>n</i> = 163)	44.9 (7.1; <i>n</i> = 123)	46.0 (5.6; <i>n</i> = 109)	0.82 (F(2542) = 0.20)

Statistically significant improvement in all scores over time in main effects only models

^aFrom a mixed linear model employing an exchangeable correlation structure

and Standard-of-Care groups. We did, however, find suggestive evidence of improved retention in care in a subset of patients who were stably housed at baseline. In addition, among those in the Peer intervention group who completed all 7 educational sessions in the intervention model, there was an overall statistically significant effect with respect to retention in care as well as a suggestive improvement in viral suppression at the end of the study period. We also found a significant protective effect of increased face-to-face encounters by peers for retention in care. These subgroup-specific results are consistent with expectations from the literature on social determinants of health, particularly with respect to material hardship, such as housing instability [27].

These results, though suggestive and clinically plausible, however, should be interpreted with caution given their secondary nature in this study and any statistical significance should be interpreted cautiously with respect to the possibility of inflated Type I error. To provide additional statistical perspective on our results, it should be noted also that with a sample size consistent with this study, it would have been necessary to observe a 4-month gap rate of 24% in the peer group compared to 39% in the standard-of-care group to achieve 80% power. Also, with respect to the significant interactions observed with respect to unstable housing status, samples consistent in size and distribution with our findings would have 68% power with an alpha of 0.05. To achieve 80% power for these interaction tests, we would have needed approximately 50 additional subjects per treatment group.

While we found improvements over time in HIV knowledge, self-efficacy and health-related quality of life, we did not find significant differences over time between the peer intervention and standard of care groups. There are a number of reasons that could explain these findings. Our sample in both study groups were living with HIV for an average of 7 years and thus may have been fairly knowledgeable about HIV and its effects. Moreover, the majority of the sample had been engaged in care at a participating Ryan White site, which compared to other health care providers, have a long history of providing culturally competent HIV medical and social support services.

Similar to other studies we did not find a significant effect in intention-to-treat analyses of the peer intervention on viral suppression [17]. We did find suggestive evidence that the peer intervention group improved retention in HIV primary care over time compared to the standard of care group, but this did not translate to viral suppression. Other studies of chronic conditions that used peer interventions to educate and support treatment adherence such as in diabetes have similarly found mixed results with respect to achieving clinical outcomes [28]. The findings highlight that achieving clinical outcomes such as viral suppression, is multifaceted and peer support may be useful in

combination with other interventions to address some of the personal and social determinants of health outcomes in patients who have fallen out of care or are new to care.

Our study highlights the importance of the instrumental and informational support in the peer role as a member of the HIV care team. This could result from patients viewing the peer as a trusted source of information and thus may be more likely to act or change their behavior on the information shared from the peer [29]. In addition, peers may be able to communicate complex information about HIV and its treatment in a manner that is easily understood and relatable to a patient. Since all these programs occurred in high volume urban clinics, peers unlike other health care team members, were able to spend more concentrated time and with patients thus providing the additional effort to keep the patient engaged in the clinic.

Our findings also highlight that success is also dependent on the frequency of contact with the peer and the earlier, intensive contact can have a positive impact on reducing the likelihood of having a gap in care. This suggests that peer-patient relationship requires time, effort and interest as being beneficial to the patient. Other studies using both non-peer and peer outreach workers also found that the amount of contact with hard-to-reach PLWHA reduces the likelihood of a gap in care [23].

Our study also noted that patient characteristics, such as being stably housed, affect the impact of peer interventions on retention in care. In a recent editorial [30], Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases, noted that “linking infected individuals to medical care; working to keep them in care; and providing anti-HIV drugs... requires careful attention to barriers to care such as poverty, substance abuse, and housing and food insecurity. Globally and domestically, we have not yet achieved this”. In this context, the results of our study are not surprising. In our study, peers were not tasked or trained to assist patients with directly obtaining housing services which was a role for the HIV case manager on the health care team. Approximately two-thirds of the sample described themselves as currently homeless or in a temporary living situation. Thus for most of the participants housing was a greater priority thus they may be less likely to spend time with a peer and rather seek services of other members of the HIV care team or turn to outside referrals for assistance. Future programs that utilize peers may consider the need to train peers about the housing referral system in their area and how to support case managers in assisting patients with obtaining housing.

Our study has a number of strengths. To our knowledge it is the first randomized trial of HIV peer support interventions that examined longer term health and clinical outcomes up to 12 months among ethnic minority patients hardest to reach in the United States: the at-risk newly diagnosed

with HIV and those who had fallen out of care. The study highlights the significant impact peers have on retention in care, especially for reaching patients who may be challenging or responsive to the health professional in adapting healthy behaviors. Peers, people who have a shared and lived experience with HIV, may be able to share common beliefs and practice that bring credibility to a person who does not perceive themselves to be sick or is wary of the health care system due to previous poor treatment. Peers may also through their emotional support and mentoring roles help people living with HIV/AIDS cope with their illness. Our study highlights the role of education, information support, and frequency of contact that contribute to the patient retention in care.

Our study also had a number of limitations. The results of this study can be generalized only to urban sites with sizable populations of people living with HIV/AIDS in the United States who are of racial and ethnic minorities. While the three sites studied had similar models of HIV service delivery as Ryan White funded providers, there were variations in their local implementation of the intervention. One site only included men in the study due to an already existing peer program for women as part of their HIV services. In addition, staff turnover during the study may have affected the quality of peer-client relationship, as the remaining peer worked with a larger caseload of patients. Also, patients starting with a new peer had to re-establish and build trust in the relationship. The actions of study and clinic staff further may have been a sufficient trigger to re-engage patients in the standard-of-care group back into care and maintain their adherence. In addition, we cannot rule out the possibility of contamination across groups by either study staff, peers or case managers who may have unintentionally provided support and informational services to the standard-of-care group in an effort to maintain patient retention in care or between patients in the peer and standard-of-care groups. We did, however, provide training to site staff on the study protocol in order to minimize the likelihood of such contamination.

Our findings highlight that effective peer programs should provide adequate training and supervision for peers as part of the care team. In addition, although our peer intervention did not result in increased viral load suppression relative to the standard-of-care, peers can have a successful impact on patient re-engagement and retention in care if given specific tasks, such as education support, as part of the care team. These tasks should be clearly delineated between other health staff to avoid duplication. In addition, for clients with multiple co-morbidities and unmet service needs, such as housing, identifying the specific supportive tasks for a peer to assist the patient is crucial. Future studies in this population should be designed to be able to definitively assess the differential effects of peer interventions by the presence and absence of material hardship, including housing stability.

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Compliance with ethical standards

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

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committees and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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