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Journal

AIDS Patient Care and STDs, 32(11)

ISSN

1087-2914

Authors

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Publication Date

2018-11-01

DOI

10.1089/apc.2018.0128

Peer reviewed

AIDS PATIENT CARE and STDs Volume 32, Number 11, 2018 © Mary Ann Liebert, Inc. DOI: 10.1089/apc.2018.0128

Multi-Site Evaluation of Community-Based Efforts to Improve Engagement in HIV Care Among Populations Disproportionately Affected by HIV in the United States

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Abstract

This study assesses effects of a community-based intervention across seven sites in the United States on HIV care utilization and study retention, among people living with HIV (PLWH). A two-armed study was conducted from 2013 to 2016 in each of seven community-based agencies across the United States. Each site conducted interventions involving community engagement approaches in the form of case management or patient navigation. Control conditions were standard of care involving referral to HIV clinical care. Participants (N=583) were adults reporting erratic or no HIV care in the past 6 months. Longitudinal survey data on demographics, behavioral risks, and HIV care were collected from participants at baseline, before service delivery, and at 6-month follow-up. Unadjusted and adjusted generalized linear mixed models were used to assess the intervention effects on HIV care utilization and study retention. Participants were majority black (75.5%), cisgender male (55.1%), and heterosexual (55.4%). No significant intervention effect was observed on HIV care utilization, although both groups improved significantly over time [adjusted odds ratio (AOR): 2.09, 95% confidence interval (CI): 1.30–3.37]. Intervention participants were more likely to be retained in the study (AOR: 1.50, 95% CI: 1.03–2.20). Community intervention did not affect HIV care utilization more than standard of care, but intervention participants were more likely to be retained in the study, suggesting that such approaches support relationship building in ways that can facilitate follow-up of socially vulnerable PLWH. More research is needed to understand how such community efforts can support better HIV care utilization in these populations.

Keywords: HIV interventions, care continuum, community-based interventions, disparities

Introduction

TIMELY HIV DIAGNOSIS and sustained engagement in HIV care are critical to the long-term health of people living with HIV (PLWH), and for the reduction of HIV transmission through improved viral suppression. ^{1,2} More than 90% of new HIV infections in the United States are attributed to PLWH who are not virally suppressed because they are undiagnosed or are diagnosed but not engaged in HIV care. ³ In 2010, the first National HIV/AIDS Strategy called for improved HIV testing and treatment outcomes among communities disproportionately affected by HIV, specifically lower income and underrepresented minorities in urban areas

and in the rural South, substance use-affected populations and sexual and gender minorities.⁴ In response, Kaiser Permanente launched the *Kaiser Permanente HIV Test and Treat Initiative* (KP Test and Treat) in 2011 to support the implementation and evaluation of community-led interventions across the United States designed to increase HIV care utilization among PLWH.

Populations at increased risk for HIV/AIDS (e.g., racial, sexual, and gender minorities) are also those with intersecting vulnerabilities (e.g., poverty, trauma, injection drug use, and stigma) that exacerbate HIV risk and delayed diagnosis, and reinforce disparities in access to HIV-related services and treatment outcomes if HIV-infection occurs.^{4–9}

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Meetings at which part of the data were presented: preliminary findings were presented at the Kaiser Permanente National HIV/AIDS, Hepatitis, and STI Conference.

Poor and underrepresented minority populations are less likely to receive healthcare generally, especially in the absence of healthcare safety nets. ^{10,11} Community-based efforts are recommended to reach populations most vulnerable to HIV and to allow for more culturally tailored and sustainable interventions. ⁴ Unfortunately, most studies aimed at increasing HIV testing and engagement in care among PLWH in the United States are clinic based, ¹² limiting their reach to most vulnerable populations. This KP Test and Treat initiative was developed to enable community-based agencies and programs to implement innovative approaches, capable of reaching and supporting socially vulnerable PLWH to engage in HIV care. This article offers findings from the cross-site evaluation of this initiative.

Methods

KP Test and Treat supported seven unique sites to implement and evaluate innovative approaches to community-based outreach to PLWH focused on linkage to or retention in HIV care. Sites were selected via a competitive request for proposals issued in 2012 and 2013 (see Table 1 for details on study sites and interventions). A cross-site evaluation was undertaken to assess the initiative's impact on HIV care utilization 6 months after enrollment. Evaluation data were collected from the period 2013 to 2017.

Study design

Each site conducted a two-armed study comparing intervention and comparison groups, either with a randomized control trial or a quasiexperimental design (Table 1). Control conditions also varied by site (i.e., attention control, waitlist control, or standard of care control). All participants were assessed via surveys at baseline and 6-month follow-up, administered by their local evaluation teams.

Recruitment and sample

All seven sites served specific priority populations disproportionately affected by HIV/AIDS, including black and Latino/a men and women, transgender women, men who have sex with men, people coming out of incarceration, and substance using populations. Sites were based in major metropolitan areas on the east and west coasts, the suburban mid-Atlantic, and the rural southeast (Table 1). Sites recruited (1) HIV-negative adults (aged 18+ years) within their target population for HIV testing, and/or (2) PLWH who were not currently in care (i.e., newly diagnosed and never linked), or tenuously engaged in HIV care (i.e., inconsistent use of care across the past year or no antiretroviral therapy (ART) use in the past 6 months).

Intervention

For this initiative, interventions at each site were community based and delivered via trained peers or community members serving as case managers ^{13–16} or patient navigators ^{17,18}; these interventionists elicited information regarding clients' social and healthcare needs and offered personalized approaches to help clients connect to services to meet these needs (Table 1). Interventions all included one-on-one sessions delivered via direct face-to-face contact, although the rural site did use short message service (SMS) messaging for

follow-up. ¹⁹ Structural supports (e.g., transportation and food security) were also provided due to high social needs of populations served. ²⁰ As all interventions used a community-based strategy and personalized connection to link participants to healthcare, we aggregated data across sites to assess effects of the initiative as a whole, relative to their control groups.

There was some variation by site in intervention approaches as well as population of focus. Group interventions, in addition to one-on-one sessions, were included in interventions for women to build social support²¹; women-focused programs also reported assessment and linkage to services for trauma from violence. One site also used groups for nutrition education.²⁰ Theoretical underpinnings of approaches also varied and included strength-based case management, traditional case management (assessment and referral for service needs), ^{15,16} patient navigation, ^{12,17,18} motivational interviewing/motivational enhancement, ^{13,14,16,21-24} and psychoeducational counseling.²⁵ Number of sessions and intervention duration also varied by site. Hence, although sample sizes were small within each site, exploratory analyses were used to examine intervention effects by site.

Procedure

On enrollment, participants (N=583) were consented and completed a baseline survey administered by a trained agency or external evaluation staff. Surveys were conducted privately and completed on paper or using mobile tablets, as per agency preference. Participants were then allocated to either an agency-specific intervention designed to support engagement in HIV clinical care or the agencies' comparison group as per each site's evaluation design (Table 1). Sixmonth surveys were also conducted by agency or evaluation staff. Remuneration for study participation varied from \$10 to \$25, reflecting each agency's goal to be responsive to their clients' needs and maintain an established rapport with their respective communities. All study procedures were approved by the local institutional review boards of each site and/or the University of California, San Diego. This study was registered with clinicaltrials.gov on May 29, 2013 (Clinical Trials No.: NCT01867177).

Measures

Sociodemographic items included age (continuous), race (white, black, Hispanic/Latino, and other), sexual orientation (heterosexual, lesbian/gay/queer, and bisexual), and gender identity (cisgender man, cisgender woman, and transgender woman [male-to-female]).

Our primary outcome was HIV care utilization, which relied on self-report due to the nonclinical nature of the initiative. We limited our outcome to reports of CD4 testing to ensure the care appointment recalled focused on HIV care; with a focus on HIV care utilization in the past 6 months, measured at both baseline and 6-month follow-up. To further explore change in the primary outcome over time, a variable henceforth referred to as "Engagement in Care" was created, with four categories:

- 1. No engagement (having no HIV care appointment in the past 6 months at baseline or follow-up),
- 2. Loss to care (having an HIV care appointment in the past 6 months at baseline but no follow-up),

Table 1. Overview of Community-Based Sites, Populations Served, Interventions, and Within-Site Study Designs

Priority propolation and agency type Priority propolation and agency type Priority propolation Esistence-based intervention Total Continued and Textual Angeles, CA (i = 104) African Angeles, CA (i = 104) Ange				the contract of the contract o	in the state of th	1
Health Center with Wingaround Services* Los Angeles, C.A. (n = 104) Wingaround Services* Los Angeles, C.A. (n = 104) An	\overline{T}	ocation and agency type	Priority population and recruitment	Evidence-based intervention	Innovations made to evidence-based approach	Site study design, control condition
STTE 2 Transgender women of One-on-one MEI ^{2,2,2,2} Organization with centured via community outtest and flicts, pain community outtest and flicts, pain community outtest and social media such as Facebook STTE 3 Women of color content and licts, pain community outtest and flicts, pain community outtest and flicts and pain intervention and support and visit suit of flicts and pain intervention and support and visit suit of flicts of pain intervention and support and visit suit of flicts. Pain community outteach by case manager and support and visit suit of flicts and pain intervention and support and visit suit of flicts. All paints are connection to police to support and visit suit flicts. All paints are connection to police to support and visit suit flicts. All paints are connection to police to support and visit suit flicts. All paints are connection to police to support and visit suit flicts. All paints are connection to police to support and visit suit flicts. All paints are connection to police to support and suit connections aroung clients. All paints are visit of prison re-entry and social services and food and social services and food and social services and food and social services and flood connection and social services and food and social services and food starter kit and food pantry access.	L AS	Health Center with Wraparound Services ^a Services Angeles, CA $(n = 104)$	African American and Latino MSM Recruited in bath houses and via street outreach	One-on-one strengths-based CM ^{14.15} Up to five strengths-based CM sessions over 6-month follow-up period Delivered by peer case manager	Adapted for delivery in community outreach settings, specifically bath houses and skid row to reach vulnerable MSM of color. Administered in Spanish as well as English; facilitated linkage to clinics known for providing confidential care to undocumented individuals CMs connected clients to social services (shelters, treatment programs) sensitive to MSM of color and undocumented individuals.	RCT Standard of care: referral to clinics
Women of color Women of color Women of color Recruited via clinic Recruited via clinic Recruited via clinic Recruited via clinic CMs met weekly with clients, offering community outreach Prison re-entry Prison re-entry Prison re-entry Prison re-entry Prison re-entry Cman group of a agency entry Recruited at agency entry Recruited at agency entry CMs met with clients weekly and social services and food delivery. Nutrition counseling was elivered by elivery. Nutrition counseling was related to since in indervention and social services and food delivery of the prison releases and food delivery. Nutrition counseling was elived to support and collaboration and social services and food delivery over an 8-session group of the prison releases. Recruited via clinic may gap and support and social services and food delivery. Nutrition counseling was delivered by: peer case manager and a food starter kit and food pantry access.	SZ O	iTE 2 Von-profit Research Organization with Transgender Drop-in- Center Dakland, CA $(n = 50)$	Transgender women of color Recruited via community outreach via media outlets and fliers, palm cards, and social media such as Facebook	One-on-one MEI ^{23,25} MEI sessions over a 4- to 6-week period including two, digital storytelling sessions plus a group empowerment program (weekly support group) Delivered by peer health educator also serving as case manager		Standard of care: 1 h. HIV education session and a session on risk reduction counseling
Prison re-entry One-on-one CM for prison releasees 16 Recruited at agency entry and group nutrition education 2 CMs met with clients weekly and outside of prison. Offered support to connect to health and social services and food elivery. Nutrition counseling was enhanced via a food starter kit and food pantry access.		ITE 3 AIDS Service Organization Oakland, CA ($n = 85$)	Women of color Recruited via clinic relationships and community outreach	One-on-one CM with patient navigation ^{12,18} and group MI ²² CMs met weekly with clients, offering patient navigation as needed. Group MI was a weekly drop-in group to foster peer motivation and support. Delivered by case manager	Adapted to include trauma informed care for women affected by violence and stigma. They also provided social support and visits during palliative care. Gender tailored to consider motherhood responsibilities and sensitivities toward health needs related to sex work and substance use. Specifically, this meant greater transportation support and child care considerations, as well as connection to police to support nighttime outreach efforts. Group MI emphasized group support due to inadequate social connections among clients.	RCT Standard of care: Access to weekly support group and monthly meetings with case manager
		ITE 4 Independent of the content of Releases with Mraparound services and Island, NY $(n = 96)$	Prison re-entry Recruited at agency entry from Riker's Island	One-on-one CM for prison releasees ¹⁶ and group nutrition education ²¹ CMs met with clients weekly and offered support to connect to health and social services and food delivery. Nutrition counseling was delivered over an 8-session group intervention Delivered by: peer case manager and a nutritionist	Provided restorative justice-centered care, emphasizing rights to re-entry into life outside of prison. Nutrition efforts included weekly food delivery to clients, with check ins on medication needs during those visits. Nutrition counseling emphasized cooking skills and foods that could be kept without refrigeration and over long periods. Food security was enhanced via a food starter kit and food pantry access.	Quasiexperimental Standard of care: postrelease CM services supporting linkage to HIV and health services

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(CONTINUED)	
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Location and agency type	Priority population and recruitment	Evidence-based intervention	Innovations made to evidence-based approach	Site study design, control condition
SITE 5 Health Center with a Dropin Center for substance users, Needle Exchange and Wraparound services ^a Newark, NJ $(n=101)$	People who use/inject drugs Recruited from needle exchange, the drop-in center, and outreach	One-on-one MI ^{17,23} CMs delivered weekly MI sessions for 6 weeks, as well as up to 3 medical CM visits per week to support MIP (Modelo de Intervencion Psicomedica), ¹⁷ psychosocial counseling with patient navigation. Delivered by: case managers/patient navigators	The primary innovation of this approach was it was used in the drop-in center setting, and emphasis on harm reduction.	Quasiexperimental Standard of care: access to medical CM in a different HIV clinic setting
SITE 6 AIDS Service Organization Prince Georges Co., MD (n=43)	Low-income African Americans and African immigrants Recruited from clinical listings and community outreach	One-on-one strengths-based CM ^{14,15} Community outreach and up to 5 strengths-based CM sessions to facilitate navigation to social services over a 6-month follow-up period. Delivered by community health workers serving as patient navigators	Adapted for delivery in community outreach settings, specifically via home visits in rural/suburban areas with African American and African immigrant populations affected by HIV.	Quasiexperimental Standard of care: passive referral to HIV care and clinic- based CM services
SITE 7 Research Organization with Multi-site Community Outreach Program NE, NC (n = 104)	Rural and suburban African Americans (primarily) Recruited from clinical listings and community outreach	One-on-one patient navigation, ^{12.18,19} psychoeducational skills-building, ²⁶ mobile messaging-SMS ²⁰ Patient navigation and six skills-building modules (~ 1 h each) focused on activating their care. Skills building was available as group sessions, but most opted for one-on-one session delivery. Opt-in health promotion-focused SMS was also available.	Due to the focus on rural and low literacy populations, modules emphasized skills and knowledge building as well as patient navigation. Individual sessions and use of SMS facilitated reach to this rural population. Navigation and skills building components were delivered back to back to reduce transportations burdens for clients and CMs. Home visits were conducted. SMS and skills building modules could include opt-in for general health promotion messages (e.g., dental health and smoking cessation) or specific HIV care messaging.	Quasiexperimental Standard of care: referral to clinical care

^aWraparound services (e.g., mental health, substance abuse treatment, housing assistance—specific services varied by site).

CM, case management; MEI, motivational enhancement intervention; MI, motivational interviewing; MSM, men who have sex with men; RCT, randomized control trial; SMS, short messaging service (i.e., text messages)—phones were not provided to participants.

3. (Re)engagement in care (having no appointment at baseline but one at follow-up), and

4. Continuous care (having an appointment at both time points).

The HIV care variables were developed based on the Centers for Disease Control and Prevention's (CDC's) definition of HIV medical care (receipt of ≥1 CD4 or viral load tests) and continuous care (≥2 CD4 or viral load tests performed at least 3 months apart). The latter variable was modified for this study to a 6-month time frame due to the timing of survey data collection used in this study.

Our secondary outcome was study retention, which was based on whether or not the participant was reached and participated at 6-month follow-up. This secondary outcome is a proxy for whether or not the intervention facilitated better agency engagement with socially vulnerable PLWH.

Covariates included study site (agency), time since HIV diagnosis (dichotomized as <12 months or ≥12 months), history of incarceration (never, in the past 12 months, or yes, but not in the past 12 months), being medically insured (yes, no), and homelessness (defined as spending at least 1 day on the streets or in a housing shelter in the past 90 days). We also included history of sexual abuse and substance use based on baseline analyses from this study, indicating the importance of these on HIV care utilization. ²⁷ Lifetime sexual violence

was defined as ever "having been forced or pressured for sex" or having someone "physically hurting the sexual parts of your body, including touching that made you feel uncomfortable." To measure drug and alcohol-related risk behaviors, the TCU-DS2²⁸ and an adapted version of the AUDIT-10 (items 1–3, 9–10)²⁹ were used, respectively. These behaviors were defined as any self-reported illicit drug use (excluding marijuana) in the past 30 days or binge drinking in the past 30 days (\geq 5 drinks in one setting; adapted from AUDIT-10 item 3).

Statistical analyses

As noted above, data were aggregated across sites, by intervention and control conditions. Descriptive statistics, Pearson's chi-square tests, and independent samples Student's *t*-tests were used to compare participants across demographic characteristics and outcomes by group assignment, site, and retention in study. Unadjusted and adjusted generalized linear mixed model (GLMM) longitudinal logistic regression was used to assess the intervention effect over time on HIV care utilization (primary outcome), with a random subject effect to account for within-subject correlations. Adjusted models included the above-noted covariates. This "difference-in-differences" analysis amounts to testing for a statistical interaction between time and intervention group in

Table 2. Sample Characteristics at Baseline and Follow-Up of the Total Sample (N=583) and by Group Assignment

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Characteristic	Total sample (N = 583), n (%)	Intervention (n = 288), n (%)	Control (n = 295), n (%)	t-Test or chi-square (df)ª	p
Baseline					
Age in years, mean (SD) Gender	43.4 (11.6)	43.2 (12.0)	43.6 (11.3)	0.41 (580) 0.54 (2)	0.679 0.762
Cisgender man	321 (55.1)	163 (56.6)	158 (53.6)	` '	
Cisgender woman	199 (34.1)	95 (33.0)	104 (35.3)		
Transgender woman	63 (10.8)	30 (10.4)	33 (11.2)		
Sexual orientation				0.44(2)	0.801
Heterosexual	315 (55.4)	156 (55.7)	159 (55.0)	` '	
Lesbian/gay/queer	165 (29.0)	83 (29.6)	82 (28.4)		
Bisexual	89 (15.6)	41 (14.6)	48 (16.6)		
Race/ethnicity				0.58 (3)	0.900
White	28 (4.8)	15 (5.2)	13 (4.4)	()	
Black/African American	440 (75.5)	219 (76.0)	221 (74.9)		
Hispanic/Latino	88 (15.1)	42 (14.6)	46 (15.6)		
Other	27 (4.6)	12 (4.2)	15 (5.1)		
Past 90 days homelessness	177 (30.4)	77 (26.7)	100 (34.0)	3.64 (1)	0.056
Medically insured	484 (83.0)	235 (81.6)	249 (84.4)	0.82(1)	0.366
Prior incarceration	` '	, ,	, ,	1.16 (2)	0.560
Yes, in past 12 months	169 (29.0)	85 (29.5)	84 (28.5)	, ,	
Yes, not in past 12 months	233 (40.0)	109 (37.9)	124 (42.0)		
Never	181 (31.1)	94 (32.6)	87 (29.5)		
Lifetime sexual violence	192 (33.2)	93 (32.8)	99 (33.7)	0.06(1)	0.813
Illicit drug use, past 30 days ^b	111 (19.0)	53 (18.4)	58 (19.7)	0.15 (1)	0.699
Binge drinking ^b	95 (16.3)	38 (13.2)	57 (19.3)	4.01 (1)	0.045*
<1 year since HIV diagnosis	77 (13.5), 13.5 (77)	41 (14.6)	36 (12.3)	0.66 (1)	0.418

^{*}Pearson's chi-square p < 0.05.

^aIndependent samples *t*-tests were conducted for continuous variables, and Pearson's chi-square tests were conducted for categorical variables. Degrees of freedom (df) are indicated in parentheses.

^bExcluding marijuana/hashish.

SD, standard deviation.

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Characteristic	SITE I (n = $I04$), n (%)	SITE 2 (n = 50), n (%)	SITE 3 (n = 85), n (%)	SITE 4 (n = 96), n (%)	SITE 5 $(n = 10I),$ $n (\%)$	SITE 6 $(n = 43)$, n (%)	SITE 7 (n = $I04$), n (%)	Chi-square (df) ^a	d
Baseline Group assignment Intervention	51 (49.0)	21 (42.0)	45 (52.9)	51 (53.1)	43 (42.6)	18 (41.9)	59 (56.7)	7.2 (6)	0.307
Control Gender Cisgender man	53 (51.0)	29 (58.0)	40 (47.1)	45 (46.9) 93 (96.9)	58 (57.4) 42 (41.6)	25 (58.1)	45 (43.3) 57 (54.8)	735.2 (12)	<0.001***
Cisgender woman Transgender woman	0 (0.0)	0 (0.0) 50 (100.0)	77 (90.6) 8 (9.4)	1 (1.0) 2 (2.1)	27 (56.4) 2 (2.0)	18 (41.9) 0 (0.0)	46 (44.2) 1 (1.0)		7
Sexual orientation Heterosexual Lesbian/gay/queer Bisexual	9 (8.7) 71 (68.3) 24 (23.1)	36 (73.5) 9 (18.4) 4 (8.2)	54 (66.7) 9 (11.1) 18 (22.2)	65 (73.0) 17 (19.1) 7 (7.9)	69 (68.3) 16 (15.8) 16 (15.8)	22 (52.4) 17 (40.5) 3 (7.1)	60 (58.3) 26 (25.2) 17 (16.5)	144.8 (12)	<0.00 \ ***
Race/ethnicity White Black/African American Hispanic/Latino Other	6 (5.8) 43 (41.4) 48 (46.2) 7 (6.7)	0 (0.0) 42 (84.0) 4 (8.0) 4 (8.0)	7 (8.2) 68 (80.0) 4 (4.7) 6 (7.1)	5 (5.2) 68 (70.8) 20 (20.8) 3 (3.1)	4 (4.0) 86 (85.2) 10 (9.9) 1 (1.0)	0 (0.0) 43 (100.0) 0 (0.0) 0 (0.0)	6 (5.8) 90 (86.5) 2 (1.9) 6 (5.8)	136.0 (18)	<0.001***
Past 90 days homelessness Medically insured Prior incarceration Yes, in past 12 months Yes, not in past 12 mo. Never	48 (46.2) 65 (62.5) 23 (22.1) 37 (35.6) 44 (42.3)	20 (40.8) 45 (90.0) 11 (22.0) 30 (60.0) 9 (18.0)	23 (27.1) 79 (92.9) 11 (12.9) 51 (60.0) 23 (27.1)	40 (41.7) 88 (91.7) 96 (100.0) 0 (0.0) 0 (0.0)	39 (38.6) 87 (86.1) 19 (18.8) 59 (58.4) 23 (22.8)	5 (11.6) 34 (79.1) 4 (9.3) 34.9 (15) 24 (55.8)	2 (1.9)) 86 (82.7) 5 (4.8) 41 (39.4) 58 (55.8)	71.2 (6) 45.0 (6) 337.2 (12)	<0.001 *** <0.001 *** <0.001 ***
Lifetime sexual violence Illicit drug use ^{b,c} Binge drinking ^b <1 year since HIV diagnosis HIV care appointment in the root 6 months	31 (29.8) 11 (10.6) 23 (22.1) 32 (31.7) 36 (34.6)	28 (56.0) 5 (10.0) 15 (30.0) 1 (2.0) 38 (76.0)	35 (42.7) 13 (15.3) 14 (16.5) 10 (12.1) 55 (64.7)	13 (13.7) 10 (10.4) 7 (7.3) 3 (3.2) 75 (78.1)	33 (32.7) 71 (70.3) 11 (10.9) 8 (8.2) 62 (61.4)	21 (48.8) 0 (0.0) 9 (20.9) 12 (28.6) 23 (53.5)	31 (30.1) 1 (1.0) 16 (15.4) 11 (10.6) 85 (81.7)	37.1 (6) 217.2 (6) 18.1 (6) 54.4 (6) 67.1	<pre><0.001** <0.001** <0.006** <0.001** <0.001**</pre>
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Table 3. Sample Characteristics at Baseline by Site (N=583)

^{**}Pearson's chi-square p < 0.01, ***p < 0.001.

*Pearson's chi-square test statistics with degrees of freedom (df) is presented.

*Past 30 days.

*Excluding marijuana/hashish.

the longitudinal model. These findings (for effect on HIV care utilization) are presented as an adjusted ratio of odds ratios (AROR). Follow-up data were available for n=397 individuals, but n=15 were excluded due to missing values on covariates (n=15), resulting in an analytic sample of n=382.

Retention in study (secondary outcome) differences between intervention and control groups were evaluated using Wald tests of unadjusted and adjusted GLMMs. The adjusted models for all outcomes included a random effect for site and a fixed effect for time since diagnosis. All other covariates were considered for inclusion via backward stepwise model building and removed at the p > 0.15 threshold level. These analyses excluded n = 7 for whom there was insufficient time to collect 6-month follow-up data and n = 17 with missing values on covariates, resulting in a subsample of n = 559 for analyses.

Given the variation by site, we also conducted unadjusted analyses by site for the primary and secondary outcomes, using the approaches previously described. Unadjusted models were used due to small site-specific sample sizes. Descriptive analyses on engagement in care were also conducted for the subsample with follow-up data (n=397) and

depicted graphically by site and treatment arm. Small cell sizes precluded significance testing.

All statistical tests were two tailed and significance was defined as p < 0.05. Analyses were conducted using SAS software, version 9.4 (Cary, NC).

Results

Among the 583 HIV-positive baseline participants, the mean age was 43.4 (standard deviation = 11.6; range = 18–78 years), and most (86.5%) had been diagnosed with HIV for a year or more (Table 2). Over half the samples were cisgender men (55.1%), approximately one-third were cisgender women (34.1%), and 10.8% were transgender women. Three-quarters of participants were black (75.5%), and 15.1% were Hispanic/Latino; 55.4% identified as heterosexual, 29.0% as lesbian/gay/queer, and 15.6% as bisexual. Nearly a third had been homeless in the past 90 days (30.4%), and 17.0% were medically uninsured. Most (69.0%) had been incarcerated in their lifetime, and a third had experienced sexual violence (33.2%). Within the past month, nearly one in five (19.0%) had used illicit drugs and 16.3% engaged in binge drinking.

Table 4. Adjusted Intervention Effect Over Time on HIV Care Appointment in the Past 6 Months and Intervention Impact on Retention in Study

	HIV care appointment in the p	ast 6 months $(n=382)^a$	Retention in study	$(n = 559)^{b}$
Variable	AOR (95% CI) ^c	p	AOR (95% CI) ^c	p
Group assignment Intervention Control	0.91 (0.58–1.43) Ref	0.678	1.50 (1.03–2.20) Ref	0.037*
Time point 6-Month follow-up Baseline	2.09 (1.30–3.37) Ref	0.003**	_	_
Group-by-time interaction ^d Age, per year Past 90 days homelessness Yes No	1.19 (0.61–2.32) 1.02 (0.99–1.03) 0.72 (0.48–1.08) Ref	0.608 0.060 0.110	1.02 (1.003–1.04)	0.024*
Prior incarceration Yes, in past 12 months Yes, not in past 12 months Never	1.23 (0.73–2.06) 0.69 (0.45–1.07) Ref	0.042*	0.56 (0.29–1.06) 0.66 (0.40–1.08) Ref	0.137
Lifetime sexual violence Yes No	1.60 (1.09–2.35) Ref	0.016*	1.74 (1.13–2.68) Ref	0.013*
Illicit drug use ^e Yes No		_	0.41 (0.21–0.79) Ref	0.007**
<1 Year since HIV diagnosis Yes No	0.68 (0.39–1.16) Ref	0.157	1.02 (0.56–1.86) Ref	0.958

^{*}Wald p < 0.05, **p < 0.01.

^aTime 2×Time 1 analysis using Wald test of a GLMM; missing data at time 2 treated as "no"; 186 respondents removed due to no follow-up data; 15 removed due to missing values on covariates.

^bTime 2 analysis using Wald test of a GLMM; 7 respondents removed due to insufficient time to collect follow-up data; 17 removed due to missing values on covariates.

^cStudy site was treated as a random effect; omitted covariates were removed during model building.

^dAdjusted ratio of odds ratios assessing the intervention effect over time, or "difference-in-differences analysis."

ePast 30 days.

AOR, adjusted odds ratio; CI, confidence interval; GLMM, generalized linear mixed model.

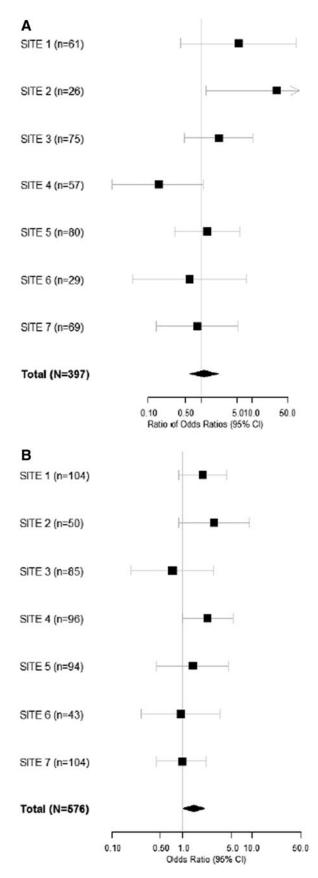


FIG. 1. Unadjusted intervention effect over time on HIV care utilization (**A**) and intervention impact on retention in study (**B**). CI, confidence interval.

Intervention and control groups were not significantly different on these variables, except for binge drinking, which was more common for control relative to intervention participants (19.3% vs. 13.2%). Significant variations in these characteristics by site were seen, in part, due to different populations targeted by study site (Table 3).

HIV care engagement

At baseline, 64.2% of participants had received HIV care in the previous 6 months, and those reporting past 6-month HIV care were significantly more likely to report that they were on ART. Difference-in-differences analyses indicate no difference between treatment groups over time on receipt of HIV care (AROR: 1.19, 95% CI: 0.61–2.32), although a significant time effect was observed across both treatment groups [adjusted odds ratio (AOR): 2.09, 95% confidence interval (CI): 1.30-3.37; Table 4]. Lifetime sexual violence and incarceration were associated with this outcome, although only the former had a clear positive relationship (AOR: 1.60, 95% CI: 1.09–2.35; Table 4). Exploratory analysis indicated that those incarcerated within the past year, relative to those previously incarcerated, had higher odds of recent HIV care (AOR: 1.77, 95% CI: 1.10-2.86), but this association did not stand up to a Bonferroni correction. Sitelevel variation in effect on this outcome was indicated by sitelevel analyses (Fig. 1A). However, subsequent exploratory analyses conducted to determine if there was heterogeneity in intervention effect on this outcome based on site differences indicated no significant heterogeneity of effect.

Descriptive analysis of engagement over time by site and treatment group indicated that 52.9% of the subsample with follow-up data (intervention and control groups combined) reported continuous HIV care, and an additional 26.5% were (re)engaged in care (Fig. 2). One in five either lost to care (9.8%) or not linked at all (10.8%). Site-level variation is indicated by descriptive data, but small numbers precluded significance testing for confirmation.

Retention in study

At 6-month follow-up, more than two-thirds of participants (68.9%, n/N = 397/576) were retained in the study. Intervention participants had higher odds of retention in study relative to those in the control group (AOR: 1.50, 95% CI: 1.03-2.20; Table 4). Bivariate analysis suggested a number of characteristics differed between those retained and those lost to study follow-up (Table 5). However, adjusted analyses indicated that participants who were older (AOR: 1.02, 95% CI: 1.003–1.04) and those who had a history of sexual violence (AOR: 1.74, 95% CI: 1.13-2.68) were more likely to be retained in the study, and those reporting past 30 days of illicit drug use were less likely to be retained in the study (AOR: 0.41, 95%: 0.21– 0.79; Table 4). Site-specific intervention effects on study retention were nonsignificant, possibly due to small cell sizes (Fig. 1B). As with our primary outcome, additional exploratory analysis was undertaken to determine if there was significant heterogeneity in intervention effect on study retention, and no significant heterogeneity in effect was observed.

Discussion

Study findings did not demonstrate significant effects of community-based intervention—in the form of case

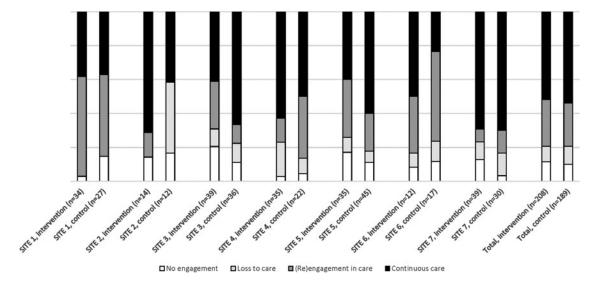


FIG. 2. Engagement in care from baseline to 6-month follow-up, intervention and control conditions by study site (n=397). No engagement = no HIV care reported at time 1 or time 2; loss to care = HIV care at time 1 but not time 2; (re)-engagement in care = no care at time 1 but care at time 2; and continuous care = HIV care at time 1 and time 2.

management and/or patient navigation—on HIV care utilization among socially vulnerable PLWH. Inadequate effects on improving HIV care utilization were likely limited partly by fairly good rates of self-reported HIV care at study start. At baseline, two-thirds of participants reported past 6-month HIV care utilization. Sites showing stronger intervention effects on use of care at follow-up were those with lower reported HIV care engagement at baseline. For this population, broader health and social welfare supports, rather than an HIV care-specific focus, may be more useful.³⁰ While most reported recent receipt of HIV care at baseline, the proportion reporting this is smaller than that seen in national surveillance data, indicating that almost three-fourths of PLWH have received care and 57% are in continuous care.²⁶ These findings showcase the heightened risks faced by the populations reached via these community-based efforts. Importantly, study findings did indicate that both intervention and control participants reported an increase in HIV care utilization over time. Improvements in engagement in care overall for study participants were observed with more than half of the sample reporting continuous HIV care at follow-up (52.9%), similar to that observed at the national level, 26 with an additional 26.5% (re)engaged in care. These findings suggest that community-based sites are able to support improvements in HIV care utilization. Current standard of care, which offered supported referral and connection to social services, may provide important elements for effectiveness that should not be lost as we continue to try to improve intervention approaches to achieve CDC-recommended 90-90-90 goals. 31 Given study findings that the intervention participants were more likely than control participants to be retained in the study, the personalized engagement through case management or patient navigation may be useful to help maintain relationships with PLWH in ways that can support better follow-up.

Additional findings from this study document that participants with a history of sexual violence were more likely to report HIV care over time and more likely to be retained in the study. These findings are consistent with baseline findings from this study documenting that among PLWH, those with a

history of sexual violence were more likely to get HIV care and social support services.²⁷ These findings run counter to those seen from the literature on intimate partner violence (IPV), demonstrating that IPV is associated with lower likelihood of HIV care, ³² as well as poorer ART adherence and viral suppression. ³³ Sexual violence disclosure may differ from IPV disclosure in terms of engagement in care. More consistent with the literature are findings that recent incarceration is related to better HIV care utilization where less recent incarceration increases risk for nonutilization of care. A systematic review of the extant literature found that while engagement in HIV care may improve during periods of incarceration, these improvements decline postrelease and may even worsen relative to preincarceration engagement in care.³⁴ Factors identified as improving engagement in HIV care postrelease included access to resources such as transportation and stable housing. This review found that interventions that helped to address these unmet needs as well as other barriers such as limited social support, stigma, and substance use have generally helped to improve postrelease engagement in HIV care.³⁴ Lack of focus on these issues by the initiatives' interventions of focus may have tempered intervention effects; a fostering environment at the agency level may also have allowed for equivalent benefits to both treatment groups.

While findings suggest that community efforts may be useful in reaching and supporting HIV care utilization, 1 in 10 participants retained in the study reported no engagement in HIV care at either baseline or follow-up. These findings suggest that there are segments of the population of PLWH who may simply not wish to engage in HIV clinical care, despite maintaining connection with community organizations serving PLWH. More research is needed to understand how these populations can continue to be served by community services in the absence of clinical care utilization. Clinical care cannot be the sole outcome or necessarily even the primary purpose for these populations, if we are to support PLWH with a care-focused model rather than strictly population-based HIV prevention efforts.

Table 5. Sample Characteristics at Baseline by Retention in Study (n=576)

			` '	
Characteristic	Retained in study, n (%)	Not retained in study, a n (%)	t-Test or chi-square (df) ^b	p
Baseline				
Total	397 (68.9)	179 (31.1)		
Group assignment			4.34 (1)	0.037*
Intervention	208 (52.4)	77 (43.0)		
Control	189 (47.6)	102 (57.0)		
Age, mean (SD)	44.0 (11.8)	41.8 (11.1)	-2.06 (573)	0.040*
Gender			23.0 (2)	<0.001***
Cisgender man	198 (49.9)	118 (65.9)		
Cisgender woman	161 (40.6)	36 (20.1)		
Transgender woman	38 (9.6)	25 (14.0)		
Sexual orientation			6.33 (2)	0.042*
Heterosexual	223 (57.2)	85 (49.4)		
Lesbian/gay/queer	102 (26.2)	63 (36.6)		
Bisexual	65 (16.7)	24 (14.0)		
Race/ethnicity			14.3 (3)	0.003**
White	12 (3.0)	16 (8.9)		
Black/African American	315 (79.4)	120 (67.0)		
Hispanic/Latino	52 (13.1)	34 (19.0)		
Other	18 (4.5)	9 (5.0)		
Past 90 days homelessness	115 (29.0)	59 (33.2)	1.02 (1)	0.313
Medically insured	374 (94.2)	179 (100.0)	10.8 (1)	0.001**
Prior incarceration			6.06 (2)	0.048*
Yes, in past 12 months	104 (26.2)	64 (35.8)		
Yes, not in past 12 months	163 (41.1)	69 (38.6)		
Never	130 (32.8)	46 (25.7)		
Lifetime sexual yiolence	144 (36.7)	48 (26.8)	5.42 (1)	0.020*
Illicit drug use ^{c,d}	76 (19.1)	31 (17.3)	0.27 (1)	0.602
Binge drinking ^c	57 (14.4)	38 (21.2)	4.23 (1)	0.040*
<1 Year since HIV diagnosis	49 (12.7)	27 (15.2)	0.66 (1)	0.417

*Chi-square p < 0.05, **p < 0.01, ***p < 0.001.

^aSeven respondents removed due to insufficient time to collect follow-up data.

SD, standard deviation.

Study findings should be considered in light of certain limitations, in particular reliance on self-reported measures. Ideally, medical records would be used to assess HIV care appointments. This was not possible. In addition, small sample sizes by sites limit our ability to infer causality at the level of the individual interventions. Further, dose or per protocol analyses were not possible due to differential lengths and contact data collection approaches across sites. Per protocol analyses may have yielded HIV care effects. Geographic representation of this study was limited to seven sites across six US cities, and sites targeted different populations of PLWH, affecting generalizability of study findings. Although variability existed among sites on the prevalence of HIV care utilization at each time point by group assignment, there was no statistically significant heterogeneity of intervention effect found among sites. We had low retention in the study, partly due to the vulnerable nature of the sample and the limited research support available at some sites. Notably, younger and substance using populations were more likely to be lost to study followup. Hence, findings may be less reflective of these groups. More research is needed to better support retention of these groups in longitudinal studies as these often include newly diagnosed individuals and those more likely to fall out of care.

In conclusion, this study finds that agencies engaging in community-based approaches to reach and retain PLWH contending with multiple forms of marginalization may offer an important complement to clinically focused retention in care programs. While the interventions undertaken by these agencies did not demonstrate greater effect on HIV care than control conditions, both treatment groups demonstrated improvements in HIV care engagement over time. Further, those involved in the interventions were more likely than control participants to be retained in the study, suggesting better relationship building through the interventions. Findings illustrate the promise of community-based organizations as a complement to clinical services to help support socially vulnerable PLWH. Such an approach should be considered part of the expansion of system-of-care factors to help PLWH achieve viral suppression, for their own health and well-being and to reduce HIV transmission.³⁵

^bContinuous variable: bivariate *t*-test statistic. We tested for equality of variances and did not reject the null hypothesis that variances were equal; a pooled estimate for equal variances was used. Proportions: chi-square test statistics with degrees of freedom (df) is shown. ^cPast 30 days.

dExcluding marijuana/hashish.

Acknowledgments

The authors thank the community-based agencies, staff, and participants of KP Test and Treat; Action.Skills.Knowledge.4Care (ASK4Care), Duke Global Health Institute (Beth Stringfield, Sara LeGrand), Fortune Society (Nilda Ricard, Brendan O'Connell, Adrian Assing), Institute for Public Health Innovation (IPHI; Abbi Charles, Bradley Boekeloo), John Wesley Community Health (JWCH) Institute (Christopher Hucks-Ortiz, Sergio Avina, Orlando Rivera), North Jersey Community Research Initiative (NJCRI; Corey Rosmarin-DeStefano, Liliane Windsor), Public Health Institute (PHI; Mariko Iwamoto, Tooru Nemoto, Jasmine McKay), Women Organized to Respond to Life-Threatening Diseases (WORLD; Cynthia Carey-Grant, Stephanie Cornwell, Samantha Feld), as well as the Kaiser Permanente Community-Based HIV Test and Treat Study Team (Alexandra Caraballo, Pamela M. Schwartz, John Edmiston, and Melissa Ramos), without whom the study would not have been possible. They are also extremely thankful for the many hours of administrative and analytic support provided by Emma Jackson, Sankari Ayyaluru, Elizabeth Gaidry, and Sanne P. Møller. The article was also supported by NIDA K01 DA039767 to L.R.S. and K01 DA036439 to L.U. This research was supported by Kaiser Permanente and East Bay Community Foundation (Grant No. 20030041). No authors hold any financial disclosures associated with this work.

Author Disclosure Statement

No competing financial interests exist.

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