Original Investigation

Effect of Patient Navigation With or Without Financial Incentives on Viral Suppression Among Hospitalized Patients With HIV Infection and Substance Use
A Randomized Clinical Trial

Lisa R. Metsch, PhD; Daniel J. Feaster, PhD; Lauren Gooden, PhD; Tim Matheson, PhD; Maxine Stitzer, PhD; Moupali Das, MD; Mamta K. Jain, MD; Allan E. Rodriguez, MD; Wendy S. Armstrong, MD; Gregory M. Lucas, MD, PhD; Ank E. Nijhawan, MD; Mari-Lynn Drainoni, PhD; Patricia Herrera, MD; Pamela Vergara-Rodriguez, MD; Jeffrey M. Jacobson, MD; Michael J. Mugavero, MD; Meg Sullivan, MD; Eric S. Daar, MD; Deborah K. McMahon, MD; David C. Ferris, MD; Robert Lindblad, MD; Paul VanVeldhuisen, PhD; Neal Oden, PhD; Pedro C. Castellón, MPH; Susan Tross, PhD; Louise F. Haynes, MSW; Antoine Douaihy, MD; James L. Sorensen, PhD; David S. Metzger, PhD; Raul N. Mandler, MD; Grant N. Colfax, MD; Carlos del Rio, MD

IMPORTANCE Substance use is a major driver of the HIV epidemic and is associated with poor HIV care outcomes. Patient navigation (care coordination with case management) and the use of financial incentives for achieving predetermined outcomes are interventions increasingly promoted to engage patients in substance use disorders treatment and HIV care, but there is little evidence for their efficacy in improving HIV-1 viral suppression rates.

OBJECTIVE To assess the effect of a structured patient navigation intervention with or without financial incentives to improve HIV-1 viral suppression rates among patients with elevated HIV-1 viral loads and substance use recruited as hospital inpatients.

DESIGN, SETTING, AND PARTICIPANTS From July 2012 through January 2014, 801 patients with HIV infection and substance use from 11 hospitals across the United States were randomly assigned to receive patient navigation alone (n = 266), patient navigation plus financial incentives (n = 271), or treatment as usual (n = 264). HIV-1 plasma viral load was measured at baseline and at 6 and 12 months.

INTERVENTIONS Patient navigation included up to 11 sessions of care coordination with case management and motivational interviewing techniques over 6 months. Financial incentives (up to $1160) were provided for achieving targeted behaviors aimed at reducing substance use, increasing engagement in HIV care, and improving HIV outcomes. Treatment as usual was the standard practice at each hospital for linking hospitalized patients to outpatient HIV care and substance use disorders treatment.

MAIN OUTCOMES AND MEASURES The primary outcome was HIV viral suppression (≤200 copies/mL) relative to viral nonsuppression or death at the 12-month follow-up.

RESULTS Of 801 patients randomized, 261 (32.6%) were women (mean [SD] age, 44.6 years [10.0 years]). There were no differences in rates of HIV viral suppression versus nonsuppression or death among the 3 groups at 12 months. Eighty-five of 249 patients (34.1%) in the usual-treatment group experienced treatment success compared with 89 of 249 patients (35.7%) in the navigation-only group for a treatment difference of 1.6% (95% CI, −6.8% to 10.0%; $P = .80$) and compared with 98 of 254 patients (38.6%) in the navigation-plus-incentives group for a treatment difference of 4.5% (95% CI −4.0% to 12.8%; $P = .68$). The treatment difference between the navigation-only and the navigation-plus-incentives group was −2.8% (95% CI, −11.3% to 5.6%; $P = .68$).

CONCLUSIONS AND RELEVANCE Among hospitalized patients with HIV infection and substance use, patient navigation with or without financial incentives did not have a beneficial effect on HIV viral suppression relative to nonsuppression or death at 12 months vs treatment as usual. These findings do not support these interventions in this setting.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01612169

JAMA. 2016;316(2):156-170. doi:10.1001/jama.2016.8914

Supplemental content at jama.com

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Lisa R. Metsch, PhD, Department of Sociomedical Sciences, Mailman School of Public Health, Columbia University, 722 W 168th St, Room 918, New York, NY 10032 (lm2892@columbia.edu).

The US National HIV/AIDS Strategy calls for improved engagement in care and increased viral suppression for people living with HIV.[1] Yet it has been estimated that only 30% of the 1.2 million persons with HIV infection in the United States in 2011 were virally suppressed,[2] and according to data collected during 1999-2007 from an observational HIV natural history study,[3] many were hospitalized with conditions preventable through HIV treatment. Substance use is likely a major factor in poor HIV clinical outcomes.[4,5] To improve their health, persons with HIV infection and substance use may require treatment for substance use disorders in concert with HIV treatment.[6,7] Few randomized clinical trials (RCTs) have evaluated such approaches.

Two potential approaches to support individuals with substance use in achieving viral suppression are (1) patient navigation (care coordination with case management) and (2) financial incentives for achieving predetermined outcomes. Previous research suggests potential for the combination of these interventions in improving engagement with substance use disorders treatment.[8,9] With regard to HIV, an RCT demonstrated efficacy of a navigation intervention to improve linkage to care, but viral suppression was not an outcome.[10] Randomized clinical trials demonstrate a positive effect of financial incentives on adherence to antiretroviral therapy (ART)[11,12]; however, effects of financial incentives on engagement in care and viral suppression have been mixed.[13-15]

Given these results, Hospital Visit as Opportunity for Prevention and Engagement for HIV-infected Drug Users (Project HOPE) was designed as an RCT of patient navigation with or without financial incentives among patients with HIV infection and substance use recruited as inpatients. The study hypothesized the proportion of patients with viral suppression (plasma HIV viral load ≤200 copies/mL) relative to nonsuppression or death would be greatest in the patient navigation plus financial incentives followed by the patient navigation group, and both groups would have higher rates of suppression than patients receiving treatment as usual.

Key Points

Question Compared with current level of care, what is the effect of patient navigation (care coordination with case management) with or without financial incentives (to achieve predetermined outcomes) on viral suppression among hospitalized patients with HIV infection and substance use?

Findings In this randomized clinical trial that included 801 patients from 11 hospitals in the United States, there was no significant difference in rates of HIV viral suppression among the study groups at 12 months (6 months after the intervention ended).

Meaning This trial shows that compared to current level of care, patient navigation with or without financial incentives did not increase viral suppression among hospitalized patients with HIV infection and substance use.

Methods

The trial had a 3 parallel-group, repeated-measures design in which inpatients with HIV infection were recruited from 11 hospitals across the United States from July 2012 through January 2014. The full protocol is available online (eProtocol in Supplement 1). The protocol was approved by institutional review boards at all participating institutions. After providing written informed consent, individuals were screened to determine eligibility. After eligible individuals were enrolled, they underwent blood draws and completed a social and behavioral assessment through a computer-assisted personal interview. Participants were then randomly assigned in equal proportions to receive either (1) 6 months of patient navigation, (2) 6 months of patient navigation plus financial incentives, or (3) treatment as usual. Patient navigation was conducted by study staff members who had previous experience in social work, case management, discharge planning, or delivery of health or prevention services. At 6 and 12 months after randomization, participants had viral load and CD4 cell counts measured and completed follow-up computer-assisted personal interviews along with urine drug and alcohol breathalyzer screens. Participants were reimbursed up to $210 for completing nonintervention-related activities. Medical records were reviewed to document use of HIV care and hospitalizations during the study period. Follow-up was completed in April 2015 and data were locked (ie, closed to further data entry) in June 2015. To facilitate screening efforts, a prescreening procedure was implemented at 9 of the 11 sites whereby patients who were ineligible according to CD4 count or viral load in medical records were not approached for screening.

Participants were eligible if they (1) were inpatients with HIV infection, (2) were at least 18 years old, (3) signed a medical record release, (4) lived in the vicinity, (5) completed the baseline assessment, (6) could communicate in English, (7) provided information on where and how to locate them, (8) had functional status of 60 or higher on the Karnofsky performance scale, (9) reported or had medical records documenting any opioid, stimulant (cocaine, ecstasy, or amphetamines), or heavy alcohol use as determined by the Alcohol Use Disorders Identification Test (AUDIT)-C[16] within the past 12 months, and (10) met one of the following requirements: had an AIDS-defining illness; had a CD4 cell count less than 350 cells/μL at their most recent screening and a viral load of more than 200 copies/mL within 6 months; or had a CD4 cell count within 12 months that was 500 cells/μL or less and their viral load was more than 200 copies/mL (or their viral load was unknown with clinical indicators that the patient was likely to have a detectable viral load).

Study Sites

The 11 hospitals included had high (≥200/y) HIV inpatient census and high prevalence of substance use among patients with HIV infection located in the following cities: Atlanta, Georgia; Baltimore, Maryland; Boston, Massachusetts; Birmingham, Alabama; Chicago, Illinois; Dallas, Texas; Los Angeles, California; Miami, Florida; New York, New York; and Philadelphia and Pittsburgh, Pennsylvania.

Randomization

A centralized data coordinating center created a computer-generated randomly permuted block randomization scheme with

equally weighted blocks of 3 and 6 to ensure relative balance across conditions over recruitment also stratified by site. Research assistants entered a participant's site information into a web-based system which generated random assignment and documentation of the participant's assignment to 1 of the 3 study groups in a 1:1:1 ratio.

Interventions

Conceptual Model

The conceptual model guiding the interventions (see the eFigure in Supplement 2) builds on 2 pathways to viral suppression. The interventions work directly to engage participants in HIV care and substance use disorders treatment simultaneously. Engagement in substance use disorders treatment should reinforce and support the engagement in HIV care and medication adherence but does not have to precede engagement in HIV care. Engagement in HIV care should lead to increased use of HIV medication, improved adherence, and HIV viral suppression.

Patient Navigation

Participants in this group had up to 11 sessions with a patient navigator during the 6-month intervention. Patient navigators received 24 hours of initial training, were monitored for fidelity, and received performance feedback from the study intervention team weekly. The first session most frequently occurred at the hospital bedside with the patient navigator working to motivate and assist participants to engage in HIV care and initiate or continue ART. Subsequent sessions were held in multiple locations (eg, patient navigator's office, in participants' living environment). Patient navigators used a strengths-based case management approach—which involves assisting patients to capitalize on their abilities, inner resources, knowledge, and motivation allowing them to better cope with ongoing life challenges,[10,17,18] and they incorporated techniques from motivational interviewing, a collaborative, goal-oriented style of communication designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion.[19] They worked with participants to (1) coordinate care with clinicians; (2) review health information; (3) overcome personal or logistical challenges (eg, access to transportation, child care); and (4) provide psychosocial support directly, by encouraging participant-identified sources of support and making appropriate referrals. Patient navigators accompanied participants to the first substance use disorders treatment and HIV care appointments. Patients in this group received no financial incentives for attending intervention sessions.

Patient Navigation Plus Financial Incentives

Participants in this group received the structured 6-month patient navigation-plus-financial-incentives intervention. The financial incentives plan was designed to enhance motivation and engagement in health-related behaviors essential to achieve the primary outcome.

Incentive amounts were designed to provide frequent positive reinforcement on an escalating scale, in amounts sufficient to motivate throughout the 6-month intervention period, for multiple targeted behaviors that mediate (eg, doctor visits, receipt of HIV medications) or interfere (eg, substance use) with achieving viral suppression. Patient navigators provided incentives for 7 target behaviors: (1) attending up to 11 patient navigation sessions (up to $220); (2) completion of required identification, insurance and other paperwork ($80); (3) 4 visits to an HIV clinic ($180); (4) attending substance use disorders treatment ($90); (5) submitting drug and alcohol-negative specimens to the patient navigator ($220); (6) having blood drawn at 2 laboratory visits ($50); and (7) having an active prescription for ART ($170). A $50 incentive was earned by participants who achieved at least a 2 $\log_{10}$ drop from baseline viral load within 4 months after randomization and $100 for a suppressed viral load at the 6-month study follow-up. A participant in the navigation-plus-incentives group could earn up to $1160 during the 6-month intervention.

Treatment as Usual

Participants in this group received the standard treatment provided at each hospital for linking hospitalized patients to outpatient HIV care and substance use disorders treatment. Designated hospital staff members, social workers, case managers, attending physicians, and infectious diseases consultants were responsible for scheduling an outpatient HIV care appointment. Standard practice for linking patients to substance use disorders treatment at most hospitals was written referral. Patient navigators did not interact with participants assigned to the treatment as usual group.

Intervention Fidelity

All patient navigation intervention sessions were audio recorded with participant consent, and 7.5% of the recordings were reviewed randomly during the trial to provide feedback to patient navigators and ensure high-quality delivery. Required activities such as assessing the patient's readiness to access substance use disorders treatment were rated using a 4-point scale: 0, not at all; 1, somewhat; 2, mostly; and 3, completely. Median ratings between 1.5 and 2.5 were classified as good, and those higher than 2.5 were classified as excellent.

Measures

HIV-1 viral load and CD4 cell count were measured by local laboratories. Urine drug screens were taken at 6 and 12 months. HIV medication adherence was measured by self-report as the percentage of pills taken in the last 30 days.[20] HIV care and substance use disorders treatment use were assessed.[21,22] Specific substances used outside of medical purposes in the last year and over the last 30 days were assessed using the substance module of the Addiction Severity Index.[23,24] Substance use severity was measured by a combination of the Drug Abuse Screening Test (DAST)-10[25] and the AUDIT.[26] Participants were counted as having a severe substance use problem if they had a 6 or higher on the DAST-10 or 6 (for women) or 7 (for men) or higher on the AUDIT. Injection drug use (IDU) was measured using an adaptation of the Global Appraisal of Individual Needs (GAIN) risk behaviors module.[27,28] Additional baseline measures, including housing stability and psychological distress, were determined using validated instruments.[29-31]

Safety

Adverse events and deaths were monitored and reported to the medical monitor and data and safety monitoring board.

Outcomes

The primary outcome was HIV viral suppression (defined as having a viral load of ≤200 copies/mL) versus HIV viral nonsuppression or death at 12 months. The protocol specified 9 HIV-related secondary outcomes with 6 reported herein. The protocol specified 4 substance use-related outcomes with 3 reported herein. The protocol also listed 5 analyses of mediators and moderators that are not reported herein. Reported secondary HIV-related outcomes included HIV viral suppression at 6 months, outpatient care with an HIV specialist, having been prescribed HIV medications, HIV medication adherence as measured by the percentage of pills taken over the last month at both 6 and 12 months. Substance use–related outcomes were assessed at 6 and 12 months and included attending professional substance use disorders treatment, level of substance use measured by urine and breathalyzer analysis, and self-report of substance use severity. For completeness, in planned analyses the primary outcome was disaggregated into viral suppression and death and in post hoc analyses professional substance use disorders treatment was disaggregated into residential outpatient treatment and into an indicator for whether medication-assisted substance use disorders treatment was used.

Analyses

The full statistical analysis plan is available (eSAP in Supplement 3). Hypotheses were tested using generalized estimating equations including both 6- and 12-month data and controlled for the baseline level of the particular outcome measure. Specific tests for the 2 follow-up assessments were done by structured contrasts based on this single repeated-measures model for each outcome. A type I error rate of 0.05 was used with 2-sided tests; a simple closed-testing procedure[32] controlled the type-I error to 0.05 per outcome. This procedure assigns the *P* value for a comparison of any 2 groups, the larger of the simple 2-group comparisons' *P* value and the 2-degree of freedom *P* value associated with the overall test of difference among all 3 groups. In the primary analysis, control variables included site of recruitment, baseline viral suppression, and an indicator for whether CD4 cell count was more than 350 cells/μL. All randomized participants were included; however, those who had not died but had missing viral load data were excluded from the primary analyses. Participants who were otherwise lost to follow-up but had viral load data available in medical records were included. Potential heterogeneity in treatment effects was examined in secondary analyses evaluating interactions of treatment with site, baseline viral suppression, stimulant use (cocaine, ecstasy, or amphetamines), and patient-reported sociodemographic characteristics: ethnicity (Hispanic or not), race (black, white, and other), and sex. Race/ethnicity and sex were included due to the documented difference in HIV care outcomes by these factors[33-36]; patients endorsed all racial categories that applied. All secondary analyses included the control variables used in the primary analysis as well as the baseline value of the particular secondary outcome.

Statistical Power

Preplanned power estimated using simulations in SAS 9.3 assumed a 12% to 15% death rate and up to 15% additional attrition at 12 months. Simulations assumed at least 12% absolute differences between treatment as usual and patient navigation groups with or without financial incentives and that suppression in the treatment-as-usual group ranged from 10% to 15%. These simulations estimated that 266 participants per group or a total of 798 participants would result in 87% power or greater for all comparisons.

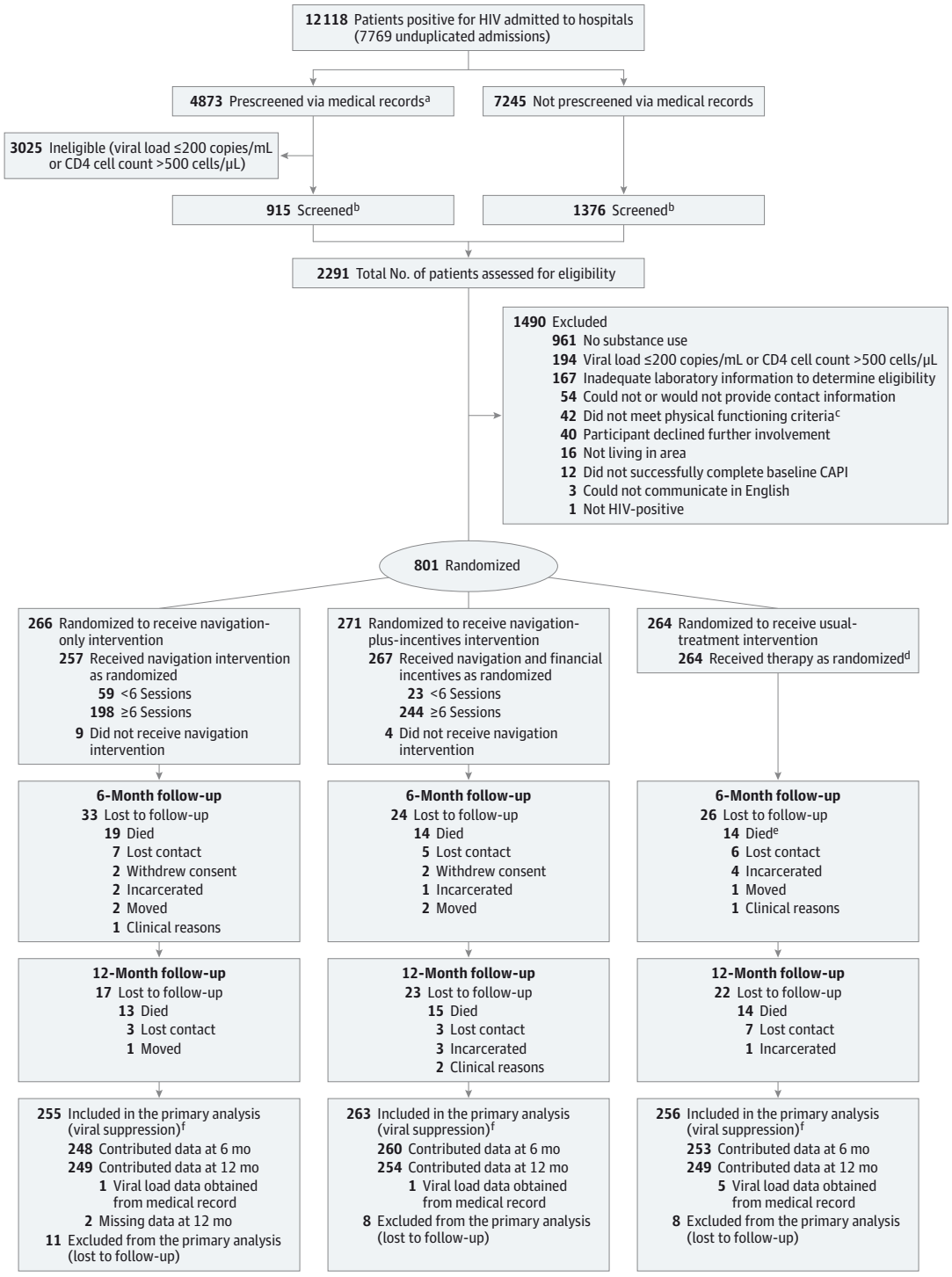
Results

There were 12 118 hospital admissions among 7769 unduplicated patients with HIV infection at the participating hospitals during the recruitment period. Prior to establishment of prescreening procedures, 1376 patients were entered into formal screening. After prescreening, 3025 patients were ineligible and 1848, eligible based on CD4 cell count or HIV viral load. A total of 915 of the 1848 eligible participants were formally screened. This resulted in 2291 patients assessed for eligibility and 801 randomized. Reasons for exclusion, randomization, and follow-up are shown in the **Figure**. The 64.5% were ineligible because of substance use criteria. The randomized sample was more likely than the nonrandomized sample to be unstably housed, incarcerated, or unemployed; lack health insurance; and have lower income and less education (**Table 1**). Approximately one-third (32.5%) of the randomized sample (**Table 2**) had a history of IDU with 18.4% injecting during the prior 12 months.

Primary Outcome

The analysis of viral suppression vs nonsuppression or death included 774 of 801 patients (96.6%) of the randomized participants with 752 (93.9%) providing data at the primary outcome assessment at 12 months. There were no differences in HIV viral suppression rates among the 3 groups at 12 months (**Table 3**; treatment success: navigation only, 35.7%; navigation plus incentives, 38.6%; and usual treatment, 34.1% of patients). Compared with usual treatment, the risk difference (RD) for the navigation-only group was 1.6% (95% CI, −6.8% to 10.0%) and for the navigation-plus-incentives group was 4.5% (95% CI, −4.0% to 12.8%). When comparing the 2 navigation groups, the RD (navigation only −[navigation plus incentives]) was −2.8% (95% CI, −11.3% to 5.6%). There was no evidence of treatment heterogeneity; the treatment interactions with site (*P* = . 83), black race (*P* = .28), Hispanic ethnicity (*P* = .84), sex (*P* = .61), or use of stimulants (*P* = .84) were not statistically significant (**Table 4**). There were however, significant main effects for these factors. Across all treatment groups, black race (33.2%) vs nonblack race (46.3%; RD, −13.1%; 95% CI, −21.7% to −4.5%), use of stimulants (32.2%) vs no use of stimulants (45.5%; RD, −13.3%; 95% CI, −21.0% to −5.7%), and enrolling in a site in the southern United States (29.0%) vs other regions (46.5%, RD, −17.5%; 95% CI, −24.5% to −10.5%) were associated with lower proportions of patients with 12-month viral suppression.

Figure. Flow of Patients Through the Project HOPE Trial



CAPI indicates computer-assisted personal interview.

[a] Consent was not required for prescreening.

[b] Informal tallies showed that refusal, being too ill and discharged before screening were equivalent reasons for not being screened.

[c] Physical functioning criteria included 26 with Karnofsky score < 60; 10 too sick to participate, and 6 cognitive functioning precluded involvement.

[d] Participants in the usual-treatment group received treatment as usual which was not tracked by the study.

[e] A patient who died in the 12 month period but was counted as lost to follow-up at 6 months.

[f] Virally suppression as treatment success includes participants with viral >200 copies/mL and treatment failure as death. This analysis includes those lost to follow-up for whom medical records of viral load were available.

Table 1. Demographics of the Screened and Randomized Samples

Characteristic	No./Total (%)			P Value[b]
	Total Screened (n = 2291)	Not Randomized (n = 1490)	Randomized (n = 801)[a]	
Women	765/2289 (33.4)	504/1488 (33.9)	261/801 (32.6)	.53
Race/ethnicity[c]				
Hispanic	246/2282 (10.8)	158/1486 (10.6)	88/796 (11.1)	.76
Black	1714/2279 (75.2)	1096/1482 (74.0)	618/797 (77.5)	.06
White	482/2279 (21.1)	330/1482 (22.3)	152/797 (19.1)	.08
Other	115/2279 (5.0)	77/1482 (5.2)	38/797 (4.8)	.66
Marital status				
Married or cohabiting	294/2275 (12.9)	204/1474 (13.8)	90/801 (11.2)	.08
Widowed, divorced, or separated	536/2275 (23.6)	355/1474 (24.1)	181/801 (22.6)	.43
Never married	1445/2275 (63.5)	915/1474 (62.1)	530/801 (66.2)	.05
Education				
<High school	762/2276 (33.5)	443/1475 (30.0)	319/801 (39.8)	<.001
High school/GED	800/2276 (35.1)	529/1475 (35.9)	271/801 (33.8)	.33
>High school	714/2276 (31.4)	503/1475 (34.1)	211/801 (26.3)	<.001
Personal annual income, median (IQR), $1000s	8.5 (6.0-13.0)	8.6 (6.8-14.0)	8.4 (4.0-11.0)	<.001
Health insurance	1649/2259 (73.0)	1115/1464 (76.2)	534/795 (67.2)	<.001
Employment status				
Working	337/2275 (14.8)	244/1474 (16.6)	93/801 (11.6)	.002
Unemployed	695/2275 (30.5)	414/1474 (28.1)	281/801 (35.1)	.001
Disabled	1131/2275 (49.7)	732/1474 (49.7)	399/801 (49.8)	.95
Other status	112/2275 (4.9)	84/1474 (5.7)	28/801 (3.5)	.02
Age, mean (SD), y	45.2 (10.7)	45.4 (11.1)	44.6 (10.0)	.08
Incarceration				
Ever	1481/2272 (65.2)	861/1473 (58.5)	620/799 (77.6)	<.001
In last 6 mo	230/2272 (10.1)	109/1473 (7.4)	121/799 (15.1)	<.001
Unstably housed				
Any of last 6 mo	659/2232 (29.5)	361/1445 (25.0)	298/787 (37.9)	<.001
Most of last 6 mo	431/2253 (19.1)	236/1462 (16.1)	195/791 (24.7)	<.001
Substance use eligible[d]				
Substance use	1292/2291 (56.4)	491/1490 (33.0)	801/801 (100.0)	<.001
Alcohol	734/2291 (32.0)	263/1490 (17.7)	471/801 (58.8)	<.001
Drugs	975/2291 (42.6)	362/1490 (24.3)	613/801 (76.5)	<.001
Club drugs[e]	85/2266 (3.8)	25/1465 (1.7)	60/801 (7.5)	<.001
Marijuana	758/2266 (33.5)	400/1465 (27.3)	358/801 (44.7)	<.001
Stimulants	883/2266 (39.0)	316/1465 (21.6)	567/801 (70.8)	<.001
Opioids	305/2266 (13.5)	133/1465 (9.1)	172/801 (21.5)	<.001
Other drugs	153/2266 (6.8)	74/1465 (5.1)	79/801 (9.9)	<.001

Abbreviation: GED, General Educational Development; IQR, interquartile range.

[a] Denominators vary due to missing data.

[b] Compares randomized vs not randomized patients.

[c] Categories are overlapping.

[d] To be substance-use eligible, the patient had to be alcohol-use eligible (Alcohol Use Disorders Identification–C score >3 for women and >4 for men) or drug-use eligible (used stimulants or opiates).

[e] Ecstasy, GHB (gamma hydroxybutyrate), or ketamine.

Secondary Outcomes

HIV Related

At 6 months 120 of 260 patients (46.2%) in the navigation-plus-incentives group were virally suppressed vs 89 of 253 patients (35.2%) in the usual-treatment group (RD, 11.0%; 95% CI, 2.5%, to 19.4%; $P = .04$). At 6 months 208 of 240 patients (86.7%) in the navigation-plus-incentives group reported that they attended HIV care visits vs 155 of 232 (66.8%) in the usual-treatment group, for an RD of 19.9% (95% CI, 12.4%-27.3%; $P = .003$) and vs 177 of 225 patients (78.7%) in the navigation-only group vs the usual-treatment group, for an RD of 11.9%, 95% CI (3.8% to 19.9%; $P < .001$). When comparing the navigation-only with the navigation-plus-incentives groups, the RD was −8.0% (95% CI; −14.9% to −1.1%; $P = .01$). Compared with the 180 of 233 patients (77.3%) in the usual-treatment group, the 221 of 242 patients (91.3%) in the navigation-plus-incentives group reported using HIV medications, for an RD of 14.1% (95% CI, 7.6% to 20.5%; $P < .001$) and vs 189 of 225 (84.0%) in the navigation-only group, for an RD of 6.8% (95% CI, −0.5% to 14.0%; $P = .05$). The RD between the navigation groups was −7.3% (95% CI, −13.3% to −1.4%; $P = .01$). None of the HIV-related secondary outcomes at 12 months were statistically different by treatment group (Table 3).

Substance Use Related

There were no significant differences among groups in urine drug screen results, self-reported days of substance use, or severity at 6 or 12 months (Table 3). Patients in both the navigation-plus-incentives (74 of 242; 30.6%) and the navigation-only groups (58 of 225, 25.8%) were more likely than patients in usual-treatment group (42 of 233; 18.0%, RD, 12.6%; 95% CI, 4.9% to 20.2%; $P < .001$ and RD, 7.8%; 95% CI, 0.2% to 15.3%; $P = .02$, respectively) to engage in professional substance use

Table 2. Demographic and Baseline HIV Care by Condition at Baseline[a]

Demographics	No./Total (%)			
	Navigation Only (n = 266)	Navigation + Incentives (n = 271)	Usual Treatment (n = 264)	Overall (n = 801)
Women	87/266 (32.7)	94/271 (34.7)	80/264 (30.3)	261/801 (32.6)
Race/ethnicity				
Hispanic	28/264 (10.6)	25/269 (9.3)	35/263 (13.3)	88/796 (11.1)
Black	204/264 (77.3)	211/271 (77.9)	203/262 (77.5)	618/797 (77.5)
White	43/264 (16.3)	57/271 (21.0)	52/262 (19.8)	152/797 (19.1)
Other	16/264 (6.1)	10/271 (3.7)	12/262 (4.6)	38/797 (4.8)
Marital status				
Married or cohabiting	32/266 (12.0)	33/271 (12.2)	25/264 (9.5)	90/801 (11.2)
Widowed, divorced, or separated	62/266 (23.3)	58/271 (21.4)	61/264 (23.1)	181/801 (22.6)
Never married	172/266 (64.7)	180/271 (66.4)	178/264 (67.4)	530/801 (66.2)
Education				
<High school	117/266 (44.0)	105/271 (38.7)	97/264 (36.7)	319/801 (39.8)
High school/GED	81/266 (30.5)	94/271 (34.7)	96/264 (36.4)	271/801 (33.8)
>High school	68/266 (25.6)	72/271 (26.6)	71/264 (26.9)	211/801 (26.3)
Personal annual income, median (IQR), $1000s[h]	8.4 (2.5-10.0)	8.4 (5.0-12.0)	8.4 (4.0-11.0)	8.4 (4.0-11.0)
Health insurance	176/264 (66.7)	182/270 (67.4)	176/261 (67.4)	534/795 (67.2)
Employment status				
Working	24/266 (9.0)	35/271 (12.9)	34/264 (12.9)	93/801 (11.6)
Unemployed	101/266 (38.0)	99/271 (36.5)	81/264 (30.7)	281/801 (35.1)
Disabled	132/266 (49.6)	131/271 (48.3)	136/264 (51.5)	399/801 (49.8)
Other status	9/266 (3.4)	6/271 (2.2)	13/264 (4.9)	28/801 (3.5)
Age, mean (SD), y	44.8 (9.9)	44.7 (10.0)	44.4 (10.1)	44.6 (10.0)
Incarceration				
Ever	214/266 (80.5)	207/270 (76.7)	199/263 (75.7)	620/799 (77.6)
Last 6 mo	41/266 (15.4)	40/270 (14.8)	40/263 (15.2)	121/799 (15.1)
Unstably housed				
Any of the last 6 mo	106/260 (40.8)	101/267 (37.8)	91/260 (35.0)	298/787 (37.9)
Most of the last 6 mo	70/263 (26.6)	60/269 (22.3)	65/259 (25.1)	195/791 (24.7)
Substance use				
Alcohol use eligible[b]	146/266 (54.9)	155/271 (57.2)	170/264 (64.4)	471/801 (58.5)
Drug use eligible[b]	258/266 (97.0)	264/271 (97.4)	258/264 (97.7)	780/801 (97.4)
Stimulant use	186/266 (69.9)	195/271 (72.0)	175/264 (66.3)	556/801 (69.4)
Opioid use	63/266 (23.7)	57/271 (21.0)	52/264 (19.7)	172/801 (21.5)
Maximum use in last 30 d, mean (95% CI), d	9.5 (7.8-11.5)	8.8 (7.3-10.7)	11.0 (9.1-13.4)	9.8 (8.7-10.9)
Severe substance use[c]	177/265 (66.8)	185/269 (68.8)	192/263 (73.0)	554/797 (69.5)
Ever IDU	90/266 (33.8)	85/271 (31.4)	85/264 (32.2)	260/801 (32.5)
IDU past 12 mo	50/266 (18.8)	51/271 (18.8)	46/264 (17.4)	147/801 (18.4)
Shared needles or paraphernalia after using	8/266 (3.0)	15/271 (5.5)	11/264 (4.2)	34/801 (4.2)
Hepatitis C virus positive[d]	101/266 (38.0)	99/271 (36.5)	101/262 (38.5)	301/799 (37.7)
Unprotected sex with HIV-negative partner[e]	42/266 (15.8)	47/271 (17.3)	49/264 (18.6)	138/801 (17.2)
Psychologically distressed[f]	145/266 (54.5)	141/270 (52.2)	132/264 (50.0)	418/800 (52.3)
Physical or sexual abuse as child	98/265 (37.0)	119/269 (44.2)	101/261 (38.7)	318/795 (40.0)
Interpersonal violence as adult	144/266 (54.1)	169/269 (62.8)	160/262 (61.1)	473/797 (59.3)
Laboratory HIV Indicators				
CD4 cell count median (IQR), cells/μL	96 (27-240)	123 (35-259)	106 (25-238)	109 (29-242)
CD4 cell count > 350 cells/μL	33/266 (12.4)	42/271 (15.5)	29/264 (11.0)	104/801 (13.0)
HIV viral load, median (IQR), 1000 copies/mL	54.0 (5.8-192.2)	53.1 (4.7-199.2)	49.4 (7.3-222.5)	52.8 (5.2-199.2)
Primary outcome at baseline				
HIV viral suppression (≤200 copies/mL)[g]	30/266 (11.3)	28/271 (10.3)	29/264 (11.0)	87/801 (10.9)
HIV viral load laboratory undetectable	10/266 (3.8)	10/271 (3.7)	12/264 (4.5)	32/801 (4.0)
Secondary outcomes at baseline				
HIV treatment				
Visited specialist				
Self-report	127/264 (48.1)	123/269 (45.7)	130/262 (49.6)	380/795 (47.8)
Medical records	48/117 (41.0)	58/131 (44.3)	55/137 (40.2)	161/385 (41.8)

(continued)

Table 2. Demographic and Baseline HIV Care by Condition at Baseline[a] (continued)

Demographics	No./Total (%)			
	Navigation Only (n = 266)	Navigation + Incentives (n = 271)	Usual Treatment (n = 264)	Overall (n = 801)
Taking medications				
Self-report	130/265 (49.1)	141/271 (52.0)	133/264 (50.4)	404/800 (50.5)
Medical records	68/199 (34.2)	72/208 (34.6)	62/197 (31.5)	202/604 (33.4)
ART pills taken in last mo, %[h,i]	52.3 (42.1-64.9)	62.7 (51.0-77.0)	56.1 (45.3-69.4)	57.2 (50.6-64.6)
Hospitalizations				
Self-report[h]	2.0 (1.8-2.2)	1.9 (1.7-2.1)	1.9 (1.7-2.1)	1.9 (1.8-2.0)
Medical records[h]	1.6 (1.4-1.7)	1.7 (1.5-1.8)	1.6 (1.5-1.8)	1.6 (1.5-1.7)
Substance use disorders treatment				
Professional treatment	44/266 (16.5)	35/271 (12.9)	46/263 (17.5)	125/800 (15.6)
Residential	23/266 (8.7)	21/270 (7.8)	25/263 (9.5)	69/799 (8.6)
Outpatient	22/265 (8.3)	15/270 (5.6)	23/263 (8.8)	60/798 (7.5)
Medication-assisted treatment[j]	18/265 (6.8)	10/271 (3.7)	14/263 (5.3)	42/799 (5.3)
Visited AA or NA	33/266 (12.4)	37/271 (13.7)	31/263 (11.8)	101/800 (12.6)

Abbreviations: AA, Alcoholics Anonymous; ART, antiretroviral therapy; GED, General Educational Development; IDU, Injection drug use; IQR, interquartile range; NA, Narcotics Anonymous.

[a] Categories are overlapping.

[b] To be substance use eligible the patient had to be alcohol-use eligible (Alcohol Use Disorders Identification Test [AUDIT]–C score of >3 for women and >4 for men) or drug-use eligible (used stimulants or opiates)

[c] Severe substance use was indicated if a patient had a Drug Abuse Screening Test (DAST)–10 score of 6 or higher or an AUDIT score of 6 or higher for women or 7 or higher for mean.

[d] Hepatitis C virus status combines self-report and medical records when available.

[e] Includes participants of unknown HIV status.

[f] Count and percentage meeting criteria for "caseness" on the Brief Symptom Inventory-18 defined as having a T score of 63 or higher on the overall score or on any 2 of the 3 dimension subscores (depression, anxiety, and somatization).

[g] Screening and eligibility were based on medical records. Baseline assessment is reported herein.

[h] A negative binomial for number data are used. The model-predicted mean (95% CI) are presented.

[i] The percentage of ART pills taken is only of those self-reporting that they were taking medications.

[j] Of those engaged in medication-assisted treatment, approximately 75% were taking methadone and 25%, buprenorphine. One person was taking oral naltrexone.

disorders treatment in the first 6 months of the trial. There was no difference in rates of substance use disorders treatment engagement at 12 months (Table 3).

Intervention Duration and Fidelity

The median number of sessions completed in the navigation-only group was 7 sessions (interquartile range [IQR], 5-10), whereas the median in the patient navigation-plus-incentives group was all 11 sessions (IQR, 8-11, $P < .001$). A total of 326 of the 4535 sessions (7.5%) delivered were rated for fidelity on a scale with a maximum score of 3. The median score on this rating varied between 2.2 and 2.75. There were no differences between the navigation groups in fidelity. A total of 267 of 271 patients (98.5%) in the navigation-plus-incentives group received a median payment of $716 (IQR, $495-$890).

Adverse Events

There was 1 adverse event, pain associated with a blood draw, in the navigation-plus-incentives group, which was rated as mild. Of the 774 patients with follow-up data, 90 (11%) died. There were no differences in the rates of death by treatment group (Table 3).

Discussion

In this study of hospitalized patients with poorly controlled HIV infection and substance use, 2 intensive but relatively short-term interventions did not result in higher rates of viral suppression relative to viral nonsuppression or death at the 12-month follow-up, which was 6 months after completion of the interventions. Across all study groups, a little more than one-third of participants achieved viral suppression at 12 months.

The intervention approach in the most enhanced group (patient navigation plus financial incentives) sought to support multiple health behaviors and linkage to both HIV care and substance use disorders treatment. It was conceptualized that once the 6-month intervention phase was concluded, the positive aspects of being engaged in HIV care and substance use disorders treatment would help overcome potential barriers to care and treatment and would translate to sustained viral suppression.[6,7] This was not the case. The observed intervention effect of viral suppression at 6 months may be explained by participants' engagement in HIV care and substance use disorders treatment, consistent with the interventions' conceptual model. It should be noted, however, that this secondary outcome is one of many secondary outcomes and even at 6 months, fewer than half of participants in the intervention group achieved viral suppression.

It is possible that the lack of substance use disorders treatment options affected study results. Participation in substance use disorders treatment was low across groups with no decrease in overall substance use and severity of use. In the study interventions, patient navigators sought to engage participants using substances with available treatment services. Several study sites did not reside in jurisdictions that offered harm reduction services. Also, the majority of the study participants used stimulants, a group that was less likely to become virally suppressed compared with those who only used opiates, alcohol, or both. Although the availability of substance

Table 3. Study Outcomes[a]

	No./Total (%)			Risk Difference (95% CI), %			*P* Value		
	Navigation Only	Navigation + Incentives	Usual Treatment	Navigation Only vs Usual Treatment	Navigation + Incentives vs Usual Treatment	Navigation Only vs Navigation + Incentives	Navigation Only vs Usual Treatment	Navigation + Incentives vs Usual Treatment	Navigation Only vs Navigation + Incentives
Primary Outcome at 12 Months[b]									
Treatment success	89/249 (35.7)	98/254 (38.6)	85/249 (34.1)	1.6 (−6.8 to 10.0)	4.5 (−4.0 to 12.8)	−2.8 (−11.3 to 5.6)	.80	.68	.68
Viral suppression (success)[c]	89/217 (41.0)	98/225 (43.6)	85/220 (38.6)	2.4 (−6.8 to 11.6)	4.9 (−4.2 to 14.1)	−2.5 (−11.8 to 6.7)	.81	.70	.70
Death (failure)[d]	32/249 (12.9)	29/254 (11.4)	29/249 (11.7)	1.2 (−4.6 to 7.0)	−0.2 (−5.8 to 5.4)	1.4 (−4.3 to 7.1)	.86	.86	.86
Secondary Outcomes at 12 Months									
HIV treatment									
Visited an HIV specialist									
Self-report	156/215 (72.6)	169/221 (76.5)	150/213 (70.4)	2.1 (−6.4 to 10.7)	6.1 (−2.3 to 14.4)	−3.9 (−12.1 to 4.3)	.34	.34	.65
Medical records	81/122 (66.4)	77/103 (74.8)	75/127 (59.1)	7.3 (−4.6 to 19.3)	15.7 (3.7 to 27.7)	−8.4 (−20.2 to 3.5)	.24	.14	.40
Taking HIV medications									
Self-report[e]	177/216 (81.9)	199/224 (88.8)	177/216 (81.9)	0.0 (−7.3 to 7.3)	6.9 (.3 to 13.5)	−6.9 (−13.5 to −0.3)	.76	.06	.06
Medical records[e]	121/164 (73.8)	136/171 (79.5)	105/156 (67.3)	6.5 (−3.5 to 16.5)	12.2 (2.7 to 21.8)	−5.8 (−14.8 to 3.3)	.14	.04	.28
ART pills taken in last mo, mean (95% CI), %[f]	79.9 (73.2 to 87.2)	81.3 (74.9 to 88.3)	83.1 (76.1 to 90.7)	−3.2 (−13.4 to 6.9)	−1.8 (−11.7 to 8.1)	−1.4 (−11.2 to 8.3)	.20	.17	.63
Hospitalizations									
Self-report[e,f]	0.9 (0.8 to 1.2)	0.7 (0.6 to 0.9)	0.7 (0.5 to 0.9)	0.2 (−0.01 to .5)	0.0 (−0.2 to 0.3)	0.2 (−0.04 to 0.5)	.24	.87	.24
Medical records[e,f]	1.1 (0.9 to 1.4)	1.0 (0.8 to 1.2)	0.9 (0.7 to 1.1)	0.2 (−0.1 to 0.5)	0.1 (−0.2 to 0.3)	0.1 (−0.14 to 0.5)	.24	.46	.28
Substance use disorders treatment									
Professional treatment	45/216 (20.8)	47/224 (21.0)	42/215 (19.5)	1.3 (−6.3 to 8.9)	1.5 (−6.1 to 9.0)	−0.2 (−7.8 to 7.5)	.68	.68	.68
Residential	24/216 (11.1)	26/224 (11.6)	16/215 (7.4)	3.7 (−1.8 to 9.1)	4.2 (−1.3 to 9.6)	−0.5 (−6.4 to 5.4)	.21	.21	.81
Outpatient	24/216 (11.1)	23/224 (10.3)	27/215 (12.6)	−1.5 (−7.5 to 4.7)	−2.3 (−8.2 to 3.7)	0.8 (−4.9 to 6.6)	.84	.84	.84
Medication-assisted treatment[e,g]	23/216 (10.7)	16/224 (7.1)	16/215 (7.4)	3.2 (−2.2 to 8.6)	−0.3 (−5.2 to 4.6)	3.5 (−1.8 to 8.8)	.41	.77	.41
Visited AA or NA	39/216 (18.1)	56/223 (25.1)	37/215 (17.2)	0.9 (−6.4 to 8.0)	7.9 (0.3 to 15.5)	−7.1 (−14.7 to 0.6)	.83	.14	.14
Substance use									
Positive urine drug screen[h]	113/166 (68.1)	105/179 (58.7)	105/160 (65.6)	2.5 (−7.8 to 12.7)	−7.0 (−17.3 to 3.3)	9.4 (−.7 to 19.5)	.73	.21	.21
Use last mo, mean (95% CI), d[f]	9.5 (7.5 to 12.1)	8.5 (6.7 to 10.8)	9.5 (7.5 to 12.1)	0.0 (−3.3 to 2.3)	−1.0 (−4.0 to 2.1)	1.0 (−2.0 to 4.0)	.66	.86	.66
Severe substance use[i]	112/216 (51.9)	111/222 (50.0)	114/215 (53.0)	−1.2 (−10.6 to 8.3)	−3.0 (−12.4 to 6.4)	1.9 (−7.5 to 11.2)	.71	.74	.71
Secondary Outcomes at 6 Months[j]									
Treatment success	97/248 (39.1)	120/260 (46.2)	89/253 (35.2)	3.9 (−4.5 to 12.4)	11.0 (2.5 to 19.4)	−7.0 (−15.6 to 1.5)	.37	.04	.11
Viral suppression (success)[c]	97/225 (43.1)	120/238 (50.4)	89/233 (38.2)	4.9 (−4.1 to 13.9)	12.2 (3.3 to 21.1)	−7.3 (−16.4 to 1.8)	.30	.03	.11
Deaths (failure)[d]	23/248 (9.3)	22/260 (8.5)	20/253 (7.9)	1.4 (−3.5 to 6.3)	0.6 (−4.2 to 5.3)	0.8 (−4.1 to 5.8)	.89	.89	.89

(continued)

Table 3. Study Outcomes[a] (continued)

	No./Total (%)			Risk Difference (95% CI), %			*P* Value		
	Navigation Only	Navigation + Incentives	Usual Treatment	Navigation Only vs Usual Treatment	Navigation + Incentives vs Usual Treatment	Navigation Only vs Navigation + Incentives	Navigation Only vs Usual Treatment	Navigation + Incentives vs Usual Treatment	Navigation Only vs Navigation + Incentives
HIV treatment									
Visited an HIV specialist									
Self-report	177/225 (78.7)	208/240 (86.7)	155/232 (66.8)	11.9 (3.8 to 19.9)	19.9 (12.4 to 27.3)	−8.0 (−14.9 to −1.1)	<.001	.003	.01
Medical records	92/131 (70.2)	103/125 (82.4)	88/151 (58.3)	12.0 (0.9 to 23.1)	24.1 (13.8 to 34.4)	−12.2 (−22.5 to −1.9)	.003	<.001	.10
Taking HIV medications									
Self-report[e]	189/225 (84.0)	221/242 (91.3)	180/233 (77.3)	6.8 (−0.5 to 14.0)	14.1 (7.6 to 20.5)	−7.3 (−13.3 to −1.4)	.05	<.001	.01
Medical records[e]	130/170 (76.5)	142/172 (82.6)	107/161 (66.5)	10.0 (0.3 to 19.7)	16.1 (6.9 to 25.3)	−6.1 (−14.6 to 2.5)	.01	.003	.45
ART pills taken in last month, mean (95% CI), %[f]	81.0 (74.4 to 88.1)	86.2 (79.7 to 93.2)	82.0 (75.2 to 89.5)	−1.0 (−11.0 to 8.8)	4.2 (−5.7 to 14.0)	−5.2 (−14.8 to 4.3)	.20	.14	.02[k]
Hospitalizations									
Self-report, mean (95% CI), %[e,f]	1.1 (0.9 to 1.4)	1.1 (0.9 to 1.3)	1.1 (0.9 to 1.3)	0.0 (−0.3 to 0.4)	0.0 (−0.3 to 0.3)	0.0 (−0.3 to 0.3)	.37	.59	.37
Medical records, mean (95% CI)[e,f]	1.8 (1.5 to 2.2)	1.9 (1.5 to 2.3)	1.7 (1.4 to 2.1)	0.1 (−0.4 to 0.6)	0.2 (−0.3 to 0.7)	−0.1 (−0.6 to 0.4)	.96	.96	.97
Substance use disorders treatment									
Professional treatment	58/225 (25.8)	74/242 (30.6)	42/233 (18.0)	7.8 (0.2 to 15.3)	12.6 (4.9 to 20.2)	−4.8 (−13.0 to 3.4)	.02	<.001	.13
Residential	30/225 (13.3)	44/242 (18.2)	24/233 (10.3)	3.0 (−2.9 to 9.0)	7.9 (1.7 to 14.1)	−4.9 (−11.4 to 1.7)	.31	.05	.14
Outpatient	32/225 (14.2)	45/242 (18.6)	17/233 (7.3)	6.9 (1.3 to 12.6)	11.3 (5.4 to 17.2)	−4.4 (−11.1 to 2.3)	.007	<.001	.10
Medication-assisted treatment[e,g]	27/225 (12.0)	13/242 (5.4)	16/233 (7.7)	5.1 (−0.2 to 10.5)	−1.5 (−5.8 to 2.8)	6.6 (1.5 to 11.7)	.03	.73	.03
Visited AA or NA	43/225 (19.1)	67/242 (27.7)	33/232 (14.2)	4.9 (−1.9 to 11.7)	13.5 (6.3 to 20.7)	−8.6 (−16.2 to −1.0)	.19	.003	.04
Substance use									
Positive urine drug screen[h]	112/171 (65.5)	121/201 (60.2)	119/182 (66.4)	0.1 (−9.8 to 10.0)	−5.2 (−14.9 to 4.5)	5.3 (−4.5 to 15.1)	.76	.54	.54
Use last mo, mean (95% CI), d[f]	7.9 (6.3 to 10.0)	8.3 (6.6 to 10.4)	8.3 (6.6 to 10.4)	−0.4 (−3.0 to 2.3)	−0.4 (−3.1 to 2.3)	0.0 (−2.7 to 2.7)	1.00	.95	.95
Severe substance use[i]	122/221 (55.2)	139/241 (57.7)	125/231 (54.1)	1.1 (−8.1 to 10.30)	3.6 (−5.4 to 12.5)	−2.5 (−11.5 to 6.6)	.48	.48	.93

Abbreviations: AA, Alcoholics Anonymous, NA, Narcotics Anonymous.

[a] Unadjusted counts, proportions and risk differences with associated 95% confidence intervals are presented. P-values are from adjusted model which included control variables. Control variables include site of recruitment, and indicator for HIV viral suppression at baseline, an indicator for CD4 cell count >350 cells/μL, and the baseline realization of the dependent measure.

[b] Viral load was determined at the 12-month assessment. Other outcomes are assessed at 12 months and refer to behaviors that occurred between 6 and 12 months.

[c] Viral suppression is ≤200 copies/mL. Analysis excludes deaths.

[d] Participants who died by 6-mo are also counted in deaths at 12 months.

[e] Due to classification error the model replaces the control for Site with an indicator for site being in the South.

[f] Model is estimated using the negative binomial link.

[g] Medications were about 75% methadone and 25% buprenorphine.

[h] Urine drug screens were done on the full sample at 6 and 12 months only. Patients in the navigation-plus-incentives group underwent additional urine drug screens as part of the intervention.

[i] Severe substance use was indicated if a patient had a Drug Abuse Screening Test (DAST)-10 score of 6 or higher or an Alcohol Use Disorders Identification Test (AUDIT) score of 6 or higher for women (men, 7 or higher).

[j] Viral load was determined at the 6-mo assessment. Other outcomes are assessed at 6 mo and refer to behaviors that occurred between baseline and 6 mo.

[k] The adjusted *P* value is significant, but the unadjusted difference is not and therefore the unadjusted 95% CI in the Table includes zero.

Table 4. Examination of Treatment Effect Heterogeneity on Viral Suppression[a]

	No./Total (%)				Risk Difference (95% CI)		
	Navigation Only	Navigation + Incentives	Usual Treatment	Total No. of Patients	Navigation Only vs Usual Treatment	Navigation + Incentives vs Usual Treatment	Navigation Only vs Navigation+ Incentives
Southern vs Northern Site[b]							
12 Months							
North	49/104 (47.1)	50/104 (48.1)	45/102 (44.1)	144/310 (46.5)	3.0 (−10.6 to 16.6)	4.0 (−9.6 to 17.6)	−1.0 (−14.5 to 12.6)
South	40/145 (27.6)	48/150 (32.0)	40/147 (27.2)	128/442 (29.0)	0.4 (−9.9 to 10.6)	4.8 (−5.6 to 15.2)	−4.4 (−14.8 to 6.0)
RD (95% CI), %	−19.5 (−31.6 to −7.5)	−16.1 (−28.2 to −3.9)	−16.9 (−28.9 to −4.9)	−17.5 (−24.5 to −10.5)			
6 Months							
North	51/103 (49.5)	58/106 (54.7)	43/102 (42.2)	152/311 (48.9)	7.4 (−6.3 to 21.0)	12.6 (−.9 to 26.0)	−5.2 (−18.7 to 8.3)
South	46/145 (31.7)	62/154 (40.3)	46/151 (30.5)	154/450 (34.2)	1.3 (−9.3 to 11.8)	9.8 (−.9 to 20.5)	−8.5 (−19.4 to 2.3)
RD (95% CI), %	−17.8 (−30.1 to −5.5)	−14.5 (−26.7 to −2.2)	−11.7 (−23.8 to 0.4)	−14.7 (−21.7 to −7.6)			
P for interaction/ main effect	.88		<.001				
Black vs Nonblack							
12 Months							
Nonblack	25/54 (46.3)	25/54 (46.3)	25/54 (46.3)	75/162 (46.3)	0.0 (−18.8 to 18.8)	0.0 (−18.8 to 18.8)	0.0 (−18.8 to 18.8)
Black	63/193 (32.6)	73/200 (36.5)	59/194 (30.4)	195/587 (33.2)	2.2 (−7.0 to 11.5)	6.1 (−3.2 to 15.4)	−3.9 (−13.3 to 5.5)
RD (95% CI), %	−13.7 (−28.5 to 1.2)	−9.8 (−24.7 to 5.1)	−15.9 (−30.7 to −1.1)	−13.1 (−21.7 to −4.5)			
6 Months							
Nonblack	22/56 (39.3)	29/56 (51.8)	29/55 (52.7)	80/167 (47.9)	−13.4 (−31.8 to 4.9)	−0.9 (−19.5 to 17.6)	−12.5 (−30.8 to 5.8)
Black	73/190 (38.4)	91/204 (44.6)	59/197 (29.9)	223/591 (37.7)	8.5 (−1.0 to 17.9)	14.7 (5.3 to 24.0)	−6.2 (−15.9 to 3.5)
RD (95% CI), %	−0.9 (−15.4 to 13.7)	−7.2 (−21.9 to 7.6)	−22.8 (−37.4 to −8.1)	−10.2 (−18.7 to −1.7)			
P for interaction/ main effect	.28		.04				
Hispanic vs Non-Hispanic							
12 Months							
Non-Hispanic	76/220 (34.5)	89/230 (38.7)	71/217 (32.7)	236/667 (35.4)	1.8 (−7.0 to 10.7)	6.0 (−2.9 to 14.8)	−4.2 (−13.0 to 4.7)
Hispanic	13/27 (48.1)	8/22 (36.4)	13/31 (41.9)	34/80 (42.5)	6.2 (−19.4 to 31.8)	−5.6 (−32.1 to 21.0)	11.8 (−15.8 to 39.3)
RD (95% CI), %	13.6 (−6.3 to 33.5)	−2.3 (−23.4 to 18.7)	9.2 (−9.2 to 27.7)	7.1 (−4.3 to 18.5)			
6 Months							
Non-Hispanic	87/220 (39.5)	107/235 (45.5)	75/220 (34.1)	269/675 (39.9)	5.5 (−3.5 to 14.5)	11.4 (2.5 to 20.4)	−6.0 (−15.1 to 3.1)
Hispanic	9/26 (34.6)	11/23 (47.8)	14/32 (43.8)	34/81 (42.0)	−9.1 (−34.2 to 16.0)	4.1 (−22.6 to 30.8)	−13.2 (−40.6 to 14.2)
RD (95% CI), %	−4.9 (−24.3 to 14.5)	2.3 (−19.1 to 23.7)	9.7 (−8.6 to 28.0)	2.1 (−9.2 to 13.5)			
P for interaction/ main effect	.84		.83				

(continued)

Table 4. Examination of Treatment Effect Heterogeneity on Viral Suppression[a] (continued)

	No./Total (%)				Risk Difference (95%) CI		
	Navigation Only	Navigation + Incentives	Usual Treatment	Total No. of Patients	Navigation Only vs Usual Treatment	Navigation + Incentives vs Usual Treatment	Navigation Only vs Navigation+ Incentives
Women vs Men							
12 mo							
Men	59/167 (35.3)	67/165 (40.6)	58/171 (33.9)	184/503 (36.6)	1.4 (−8.7 to 11.6)	6.7 (−3.6 to 17.0)	−5.3 (−15.7 to 5.2)
Woman	30/82 (36.6)	31/89 (34.8)	27/78 (34.6)	88/249 (35.3)	2.0 (−12.9 to 16.8)	0.2 (−14.3 to 14.7)	1.8 (−12.6 to 16.1)
RD (95% CI), %	1.3 (−11.4 to 14.0)	−5.8 (−18.2 to 6.6)	0.7 (−12.0 to 13.4)	−1.2 (−8.5 to 6.0)			
6 Months							
Men	72/167 (43.1)	82/172 (47.7)	62/175 (35.4)	216/514 (42.0)	7.7 (−2.6 to 18.)	12.3 (2.0 to 22.5)	−4.6 (−15.2 to 6.0)
Woman	25/81 (30.9)	38/88 (43.2)	27/78 (34.6)	90/247 (36.4)	−3.8 (−18.3 to 10.8)	8.6 (−6.2 to 23.4)	−12.3 (−26.8 to 2.1)
RD (95% CI), %	−12.3 (−24.8 to 0.3)	−4.5 (−17.3 to 8.3)	−0.8 (−13.5 to 11.9)	−5.6 (−13.0 to 1.8)			
P for interaction/main effect	.61		.36				
Stimulant vs No Stimulant Use							
12 Months							
No stimulant use	30/70 (46.5)	33/71 (46.5)	39/83 (47.0)	102/224 (45.5)	−4.1 (−19.9 to 11.7)	−0.5 (−16.3 to 15.3)	−3.6 (−20.0 to 12.8)
Stimulant use	59/179 (33.0)	65/183 (35.5)	46/166 (27.7)	170/528 (32.2)	5.3 (−4.4 to 14.9)	7.8 (−1.9 to 17.5)	−2.6 (−12.3 to 7.2)
RD (95% CI), %	−9.2 (−22.3 to 4.0)	−11.0 (−24.5 to 2.6)	−19.3 (−32.0 to −6.6)	−13.3 (−21.0 to −5.7)			
6 Months							
No stimulant use	29/69 (42.0)	39/72 (54.2)	34/84 (40.5)	102/225 (45.3)	1.5 (−14.1 to 17.2)	13.7 (−1.9 to 29.3)	−12.1 (−28.5 to 4.2)
Stimulant use	68/179 (36.4)	81/188 (43.1)	55/169 (32.5)	204/536 (38.1)	5.4 (−4.6 to 15.5)	10.6 (0.5 to 20.5)	−5.1 (−15.3 to 4.9)
RD (95% CI), %	−9.9 (−23.4 to 3.6)	−11.1 (−24.6 to 2.4)	−7.9 (−20.6 to 4.7)	−7.3 (−15.0 to 0.4)			
P for interaction/main effect	.84		.001				
Suppressed vs Not Suppressed at Baseline							
12 Months							
Not Suppressed	74/221 (33.5)	81/226 (35.8)	71/220 (32.3)	226/667 (33.9)	1.2 (−7.6 to 10.0)	3.6 (−5.2 to 12.4)	−2.4 (−11.2 to 6.5)
Suppressed	15/28 (53.6)	17/28 (60.7)	14/29 (48.3)	46/85 (54.1)	5.3 (−20.6 to 31.2)	12.4 (−13.2 to 38.1)	−7.1 (−33.0 to 18.7)
RD (95% CI), %	20.1 (0.6 to 39.6)	24.9 (5.7 to 44.0)	16.0 (−3.2 to 35.2)	20.2 (9.1 to 31.4)			
6 Months							
Not suppressed	80/219 (36.5)	98/232 (42.2)	72/225 (32.0)	250/676 (37.0)	4.5 (−4.3 to 13.4)	10.2 (1.4 to 19.1)	−5.7 (−14.7 to 3.3)
Suppressed	17/29 (58.6)	22/28 (78.6)	17/28 (60.7)	56/85 (65.9)	−2.1 (−27.6 to 23.4)	17.9 (−5.8 to 41.5)	−20.0 (−43.5 to 3.6)
RD (95% CI), %	22.1 (3.1 to 41.1)	36.3 (19.9 to 52.8)	28.7 (9.6 to 47.8)	28.9 (18.2 to 39.6)			
P for interaction/main effect	.52		<.001				

Abbreviation: RD, risk difference.

[a] Unadjusted counts, proportions and risk differences with associated 95% confidence intervals are presented. *P* values are from adjusted model which included control variables. Control variables include site of recruitment, an indicator for HIV viral suppression at baseline, and an indicator for CD4 cell count >350 cells/μL.

[b] For confidentiality reasons no data specific to sites are presented, instead we present the difference between Northern and Southern sites.

use disorders treatment in locations of study sites was not measured, this suggests the need for more acceptable or accessible interventions for substance use disorders treatment, particularly among stimulant users. In addition, it should be noted that this trial cannot rule out the possibility that financial incentives, patient navigation, or both may be effective interventions to improve outcomes for individuals already engaged in substance use disorders treatment.

Study participants represent patients with HIV infection and complex issues; many present with multiple comorbidities that exceed substance use disorders, including considerable social disadvantage. The study results raise the question of whether intensive, individual-level interventions are sufficiently broad and robust enough to improve HIV outcomes among populations currently not benefitting from treatment. Most participants were low-income persons of color who may experience negative sociocultural factors such as poverty, racism, unstable housing, HIV-related stigma, and high rates of incarceration. Systemic and structural barriers to care may be difficult to overcome with an individual-level behavioral intervention, even an intensive one; for example, this study found that black participants (compared with white participants) and participants from southern sites were less likely to be virally suppressed. This is consistent with studies that have shown demographic and geographic variation in HIV clinical outcomes.[33,37,38]

Even though the study had high retention and intervention fidelity rates, several limitations should be noted. The mean number of sessions completed by participants in the navigation-plus-incentives group was significantly higher than it was for the navigation-only group. This may result from the offer of financial incentives, which increased overall attendance in the intervention. In any case, the larger number of patient navigation sessions combined with financial incentives would have been expected to increase the likelihood of efficacy in this study group compared with treatment as usual; this was not the case. The absence of a financial incentives–only condition prevented the ability to examine the independent effect of financial incentives. Also, the secondary outcomes, use of HIV care, substance use disorders treatment, and use of ART were based on self-report, yet medical record review did confirm results for HIV care and prescription for ART. In addition, the screening process relied on historical medical records to document viral load and thus a small number of participants entered the study with viral suppression at baseline. None of these limitations are likely to have influenced the study outcome.

Conclusions

Among hospitalized patients with HIV infection and substance use, patient navigation with or without financial incentives did not have a beneficial effect on HIV viral suppression relative to nonsuppression or death at 12 months compared with treatment as usual. These findings do not support these interventions in this setting and indicate that other approaches are needed to improve HIV outcomes in this vulnerable population.

ARTICLE INFORMATION

Author Affiliations: Department of Sociomedical Sciences, Mailman School of Public Health, Columbia University, New York, New York (Metsch, Gooden, Castellón); Department of Public Health Sciences, Miller School of Medicine, University of Miami, Miami, Florida (Feaster); San Francisco Department of Public Health, San Francisco, California (Matheson, Das, Colfax); Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine, Baltimore, Maryland (Stitzer); San Francisco General Hospital, San Francisco, California (Das); University of California, San Francisco (Das); Division of Infectious Diseases, Department of Internal Medicine, University of Texas Southwestern Medical Center, Dallas (Jain, Nijhawan); Parkland Health and Hospital System, Dallas, Texas (Jain); Division of Infectious Diseases, Department of Medicine, Miller School of Medicine, University of Miami, Miami, Florida (Rodriguez); Division of Infectious Diseases, Department of Medicine, Emory University School of Medicine, Atlanta, Georgia (Armstrong, del Rio); Johns Hopkins University School of Medicine, Baltimore, Maryland (Lucas); Department of Health Law, Policy and Management, Boston University School of Public Health, Boston, Massachusetts (Drainoni); Section of Infectious Diseases, Department of Medicine, Boston University School of Medicine, Boston, Massachusetts (Drainoni, Sullivan); Ruth M. Rothstein CORE Center, John H. Stroger, Jr, Hospital of Cook County, Chicago, Illinois (Herrera, Vergara-Rodriguez); Division of Infectious Diseases, Drexel University College of Medicine, Philadelphia, Pennsylvania (Jacobson); Department of Medicine, Lewis Katz School of Medicine, Temple University, Philadelphia, Pennsylvania (Jacobson); Department of Neuroscience, Lewis Katz School of Medicine, Temple University, Philadelphia, Pennsylvania (Jacobson); Institute of Translational AIDS Research, Lewis Katz School of Medicine, Temple University, Philadelphia, Pennsylvania (Jacobson); Division of Infectious Diseases, Department of Medicine, University of Alabama at Birmingham (Mugavero); Los Angeles Biomedical Research Institute at Harbor-University of California Los Angeles Medical Center, Torrance (Daar); University of Pittsburgh, Pittsburgh, Pennsylvania (McMahon); Mount Sinai St Luke's and Mount Sinai West Hospitals, New York, New York (Ferris); Icahn School of Medicine at Mount Sinai, New York, New York (Ferris); The Emmes Corporation, Rockville, Maryland (Lindblad, VanVeldhuisen, Oden); HIV Center for Clinical and Behavioral Studies, Division of Gender, Sexuality and Health, Department of Psychiatry, Columbia University Medical Center, New York, New York (Tross); Greater New York Node, National Drug Abuse Treatment Clinical Trials Network, Substance Use Research Center, Department of Psychiatry, Columbia University, New York, New York (Tross); Division of Addiction Sciences, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, Charleston, South Carolina (Haynes); University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania (Douaihy); Western States Node, National Drug Abuse Treatment Clinical Trials Network, Department of Psychiatry, University of California, San Francisco (Sorensen); Department of Psychiatry, Perelman School of Medicine, University of Pennsylvania, Philadelphia (Metzger); Treatment Research Institute, Philadelphia, Pennsylvania (Metzger); Center for the Clinical Trials Network, National Institute on Drug Abuse, National Institutes of Health, Bethesda, Maryland (Mandler); Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, Georgia (del Rio).

Author Contributions: Drs Metsch and Feaster had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Metsch, Feaster, Gooden, Matheson, Stitzer, Das, Tross, Haynes, Sorensen, Mandler, Colfax, Del Rio.
Acquisition, analysis, or interpretation of data: Metsch, Feaster, Gooden, Matheson, Jain, Rodriguez, Armstrong, Lucas, Nijhawan, Drainoni, Herrera, Vergara-Rodriguez, Jacobson, Mugavero, Sullivan, Daar, McMahon, Ferris, Lindblad, VanVeldhuisen, Oden, Castellón, Douaihy, Metzger, Del Rio.
Drafting of the manuscript: Metsch, Feaster, Gooden, Del Rio.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Feaster, VanVeldhuisen, Oden.
Obtained funding: Metsch, Del Rio.
Administrative, technical, or material support: Metsch, Gooden, Matheson, Stitzer, Das, Lindblad, VanVeldhuisen, Castellón, Tross, Haynes, Sorensen, Mandler, Colfax, Del Rio.
Study supervision: Metsch, Feaster, Gooden, Matheson, Stitzer, Das, Jain, Rodriguez, Lucas, Nijhawan, Drainoni, Herrera, Jacobson, Mugavero, Sullivan, Daar, McMahon, Ferris, Lindblad, VanVeldhuisen, Haynes, Douaihy, Metzger, Del Rio.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Drs Metsch, Feaster, Gooden, Das, Rodriguez, Nijhawan, Mugavero, Sullivan, Daar, Douaihy, Sorensen, and del Rio and Mr Castellón report receiving grants from the National Institute on Drug Abuse, National Institutes of Health (NIH). Dr Das reports being employed (since October 2013) by and owning stock in Gilead Sciences Inc. Dr Jain reports serving on the advisory boards of Gilead Sciences and Abbvie and receiving grants from Gilead Sciences Inc, Merck Sharp & Dohme Corp, Bristol-Myers Squibb, Jannssen, AbbVie, Theratechnologies, ViiV Healthcare, GlaxoSmithKline, Boehringer Ingelheim Pharmaceuticals Inc, and Vertex Pharmaceuticals. Dr Nijhawan reports receiving grants from that National Institute of Allergy and Infectious Diseases, Gilead Sciences Inc, and the University of Texas System. Dr Mugavero reports receiving personal fees from Bristol-Myers Squibb and Gilead Sciences Inc. Dr Daar reports receiving consulting fees for his institution from Bristol Myers Squibb, Gilead Sciences Inc, Merck, Teva, and ViiV Healthcare. Dr McMahon reports grants from the University of Pittsburgh. Drs Lindblad and VanVeldhuisen report contract work from the National Institute on Drug Abuse. Dr Douaihy reports receiving grants from the Health Resources and Services Administration, Orexo, and Alkermes; and royalties from Oxford University Press for 2 academic books and from PESI Publishing and Media for 1 academic book. No other disclosures were reported.

Funding/Support: Funding for this study and analysis was provided for the study's principal investigators by the National Institute on Drug Abuse under the following awards: U10DA013720 and UG1DA013720 (Drs José Szapocznik and Lisa R. Metsch); U10DA013035 and UG1DA013035 (Drs John Rotrosen and Edward V. Nunes, Jr); U10DA013034 and UG1DA013034 (Drs Maxine Stitzer and Robert Schwartz); U10DA013727 and UG1DA013727 (Drs. Kathleen T. Brady and Matthew Carpenter); U10DA020024 and UG1DA020024 (Dr Madhukar H. Trivedi); U10DA013732 and UG1DA013732 (Dr Theresa Winhusen); U10DA015831 and UG1DA015831 (Drs. Roger D. Weiss and Kathleen Carroll); U10DA015815 and UG1DA015815 (Drs James L. Sorensen and Dennis McCarty); U10DA020036 (Dr Dennis Daley); U10DA013043 (Dr George Woody); U10DA013045 (Dr Walter Ling); HHSN271200900034C/N01DA92217 and HHSN271201400028C/N01DA142237 (Dr Paul VanVeldhuisen); and HHSN271201000024C/N01DA102221 (Dr Robert Lindblad). Support from the University of Miami Center for AIDS Research (CFAR) (P30AI073961; Dr Savita Pahwa), the Emory University CFAR (P30AI050409; Drs Carlos del Rio, James W. Curran, and Eric Hunter), the Atlanta Clinical and Translational Science Institute (UL1TR000454; Dr David Stephens), and the HIV Center for Clinical and Behavioral Studies at the New York State Psychiatric Institute/Columbia University Medical Center (P30MH043520; Dr Robert Remien) is also acknowledged.

Role of the Sponsor: Staff of the Center for the Clinical Trials Network in the National Institute on Drug Abuse National Drug Abuse Treatment Clinical Trials Network had an advisory role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. The Center for the Clinical Trials Network in the National Institute on Drug Abuse appointed members and coordinated meetings of the data safety monitoring board. This manuscript was reviewed and approved by the Publications Committee of the National Drug Abuse Treatment Clinical Trials Network.

Disclaimer: The authors are solely responsible for the content of this article, which does not necessarily represent the official views of the National Institute on Drug Abuse. Dr Mandler, an employee of the National Institute on Drug Abuse, is an author and did review and approve the manuscript as a part of his authorship role. His role on the project is through the Center for Clinical Trials Network in the National Institute on Drug Abuse.

Previous Presentation: Results from this study were presented by Dr Metsch at the annual Conference on Retroviruses and Opportunistic Infections (CROI), Boston, Massachusetts, February 22-25, 2016. Both the abstract and presentation entitled, "A Patient Navigation/Contingency Management RCT for Hospitalized HIV+ Substance Users," are available on the CROI website. Information about the study, including the protocol, and the de-identified study data will be available at https://datashare.nida.nih.gov/ within 18 months of the date the data system closed to further data entry (June 2015), as per the procedures of the National Drug Abuse Treatment Clinical Trials Network.

Additional Contributions: We thank the following individuals for their contributions to the study. From the University of Miami Miller School of Medicine, Jose Szapocznik, PhD, Viviana Horigian, MD, and Ingrid M. Usaga, MSW, for Florida Node Alliance coordination; Terri Liguori, MEd, EdS, for national implementation coordination; Jessica Ucha, MSEd, Luis Espinoza, MD, and Michael Kolber, MD, PhD, for site coordination; Katie Klose, MSW, Lisa Abreu, MPH, and Laurel Hall, BS, for intervention delivery and data collection; Sara Clingerman, BS, for data collection; Cheryl Walker for outreach and retention assistance; Elizabeth Alonso, PhD, Silvia Mestre, MS, and Aura Pacini, CCRA, for quality assurance; Yue Pan, MS, Rui Duan, MPH, and C. Mindy Nelson, MS, PhD, for data analysis; and Kathleen Mercogliano, RN, and Sheila Findlay, MSW, LCSW, for research assistance. From Columbia University, Carrigan Parish, DMD, and Iveth Yanez, MPA, for manuscript development and D. Faye Yeomans, AS, for research assistance. From The Village South, Inc, Michael Miller, PhD, for intervention training and assistance. From the San Francisco Department of Public Health, Shannon Huffaker, NP, and Erin DeMicco, MPH, for national clinical coordination and Shawn Demmons, MPH, and Lamont Hernandez, MA, for national intervention coordination and fidelity monitoring. From the University of Washington Donald Calsyn, PhD, for intervention coordination and training. From Friends Research Institute, Robert Schwartz, MD, for Mid-Atlantic Node coordination. From Johns Hopkins University, Jack Chally, MBA, and Heather Fitzsimmons for Mid-Atlantic Node coordination; Katie J. C. Zook, CCRP, for regulatory assistance; Jeanne Keruly, MS, CRNP, and Jasmine Dixon, BS, for site coordination; Rajni Sharma, Melissa Otterbein, and Antionette McCray for intervention delivery and data collection; and Warren Lee for outreach and retention assistance. From Lumen Networks, Leonard Onyiah for development of the intervention tracking system. From the University of Texas Southwestern Medical Center, we thank Madhukar Trivedi, MD, and Robrina Walker, PhD, for Texas Node coordination; Katherine Sanchez, LCSW, PhD, for intervention training and assistance; Mora Kim, MPH, Kathryn Dzurilla, Brittany Eghaneyan, MSSW, and Stacy Abraham, MPH for site coordination and data collection; Mark Vasquez, BS, for data collection; Deneen Robinson and Orlando House for intervention delivery and data collection; Gerald Strickland for outreach and retention assistance and data collection; and Kathy Shores-Wilson, PhD, for regulatory coordination and quality assurance. From Emory University Vincent Marconi, MD, Jonathan Colasanti, MD, Christin Root, BS, and Valarie Hunter for site coordination; Marietta Collins, PhD, and Eugene Farber, PhD, for intervention training and assistance; Christopher Foster, BA, and Charles Fountain for intervention delivery and data collection; Kishna Outlaw, Kelly Dyer, BS, Brooke Peery, MPH, and Leslie McCoy, MBA, for data collection; and Ossie Williams, BS, and Kathy Traylor for outreach and retention assistance. From McLean Hospital, Roger Weiss, MD, for New England Consortium Node coordination; Kathryn McHugh, PhD, for protocol coordination and Scott E. Provost, MM, MSW, for quality assurance. From Boston University Ashley Leech for site coordination; Gena Hong, Jillian Van Zee, Eric LeFevre, and Joy Sylvester for intervention delivery and data collection; and Lynsey Avalone for data collection. From University of Cincinnati, Theresa Winhusen, PhD, and Angela Casey-Willingham, BA, for Ohio Valley Node coordination; Anne Autry, MD, for protocol coordination; Emily Dorer, BS, for regulatory coordination; and Frankie Kropp, MS, for clinical trial coordination. From John H. Stroger, Jr. Hospital of Cook County, Jeffrey Watts, MD, and Sarah Elder, LCSW, CADC, for site coordination; Fabiana Araujo, Allen Ratliff, Rona Clark, Kristin Reitz, and Gabrielle Pendley for intervention delivery and data collection; Felipe Hernandez for data collection; and Eddie Nance and Mishea Robinson for outreach and retention assistance. From the University of Pennsylvania, George Woody, MD, for Delaware Valley Node coordination; Charlotte Royer-Malvestuto, MED, MBE, and Edgar Weiss, MS, for protocol coordination; Peter Smith and Mack Taylor for outreach and retention assistance; and Lin Denton, RN, BSN, for quality assurance. From Drexel University College of Medicine, James K. Robinson, MSW, MPH, for site coordination and Stephanie Josephson, LSW, for intervention delivery and data collection. From Medical University of South Carolina, Kathleen Brady, MD, PhD, and Gail Brubaker, BS, for Southern Consortium Node coordination and Kimberly Pressley, MA, for protocol coordination and quality assurance. From the University of Alabama at Birmingham, Joseph Schumacher, MD, Karen Cropsey, MD, James Willig, MD, D. Scott Batey, MSW, and Heather Coley, MPH, for site coordination; Sandra Roberts for program coordination; DeBran Jacobs, MPH, and Stephanie Gaskin, MHA, for intervention delivery and data collection; and Juan Horton, MSW, for outreach and retention assistance. From the University of California, Los Angeles, Walter Ling, MD, and Albert Hasson, MSW, for Pacific Region Node

coordination; Mark Oyama, MBA, and Steve Shoptaw, PhD, for protocol coordination; Sandy MacNicoll, MBA, for quality assurance; Mario Guerrero for site coordination; Pedro Chavez, BA, for intervention delivery and data collection; and Vanessa Correa, BA, for data collection. From the University of Pittsburgh, Dennis Daley, PhD, and Dorothy Sandstrom, MS, for Appalachian Tri-State Node coordination; Peter Veldkamp, MD, and Caroline Baron-Myak, RN, for site coordination; Jacob Johnson, MSC, Anita Barnhart, MSW, and Walitta Abdullah, MS, for intervention delivery and data collection; and Janis McDonald for outreach and retention assistance. From New York State Psychiatric Institute, Edward Nunes, MD, and Jennifer Lima for Greater New York Node coordination; Eva Turrigiano for quality assurance; Megan Ghiroli for site coordination; and Christopher Ferraris for intervention delivery and data collection. From Mount Sinai St Luke's Hospital, Matthew Berler and Jennifer Derri for intervention delivery and data collection and Joann Gomez and Sylviah Nyamu for data collection. From the Emmes Corporation, Eve Jelstrom CRNA, MBA, for project management; Li Lu, MS, for data analysis; and Ashley Case and Jeremy Wolff for data management. The aforementioned contributors did not receive external compensation outside of their usual salary support.

REFERENCES

1. The White House Office of National AIDS Policy. National HIV/AIDS strategy for the United States: Updated to 2020. https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas-update.pdf. Accessed August 11, 2015.

2. Bradley H, Hall HI, Wolitski RJ, et al. Vital Signs: HIV diagnosis, care, and treatment among persons living with HIV--United States, 2011. *MMWR Morb Mortal Wkly Rep*. 2014;63(47):1113-1117.

3. Crum-Cianflone NF, Grandits G, Echols S, et al; Infectious Disease Clinical Research Program. Trends and causes of hospitalizations among HIV-infected persons during the late HAART era: what is the impact of CD4 counts and HAART use? *J Acquir Immune Defic Syndr*. 2010;54(3):248-257.

4. Porter K, Babiker A, Bhaskaran K, et al; CASCADE Collaboration. Determinants of survival following HIV-1 seroconversion after the introduction of HAART. *Lancet*. 2003;362(9392):1267-1274.

5. Milloy MJ, Marshall BD, Kerr T, et al. Social and structural factors associated with HIV disease progression among illicit drug users: a systematic review. *AIDS*. 2012;26(9):1049-1063.

6. Bell C, Metsch LR, Vogenthaler N, et al. Never in care: characteristics of HIV-infected crack cocaine users in 2 US cities who have never been to outpatient HIV care. *J Acquir Immune Defic Syndr*. 2010;54(4):376-380.

7. Uhlmann S, Milloy MJ, Kerr T, et al. Methadone maintenance therapy promotes initiation of antiretroviral therapy among injection drug users. *Addiction*. 2010;105(5):907-913.

8. Chutuape MA, Katz EC, Stitzer ML. Methods for enhancing transition of substance dependent patients from inpatient to outpatient treatment. *Drug Alcohol Depend*. 2001;61(2):137-143.

9. Haug NA, Sorensen JL. Contingency management interventions for HIV-related behaviors. *Curr HIV/AIDS Rep*. 2006;3(4):154-159.

10. Gardner LI, Metsch LR, Anderson-Mahoney P, et al; Antiretroviral Treatment and Access Study Group. Efficacy of a brief case management intervention to link recently diagnosed HIV-infected persons to care. *AIDS*. 2005;19(4):423-431.

11. Rosen MI, Dieckhaus K, McMahon TJ, et al. Improved adherence with contingency management. *AIDS Patient Care STDS*. 2007;21(1):30-40.

12. Sorensen JL, Haug NA, Delucchi KL, et al. Voucher reinforcement improves medication adherence in HIV-positive methadone patients: a randomized trial. *Drug Alcohol Depend*. 2007;88(1):54-63.

13. Bassett IV, Wilson D, Taaffe J, Freedberg KA. Financial incentives to improve progression through the HIV treatment cascade. *Curr Opin HIV AIDS*. 2015;10(6):451-463.

14. El-Sadr WM, Branson BM, Beauchamp G, et al. Effect of financial incentives on linkage to care and viral suppression: HPTN 065. http://www.croiconference.org/sessions/effect-financial-incentives-linkage-care-and-viral-suppression-hptn-065. Accessed January 12, 2016.

15. Solomon SS, Srikrishnan AK, Vasudevan CK, et al. Voucher incentives improve linkage to and retention in care among HIV-infected drug users in Chennai, India. *Clin Infect Dis*. 2014;59(4):589-595.

16. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. *Arch Intern Med*. 1998;158(16):1789-1795.

17. Brun C, Rapp RC. Strengths-based case management: individuals' perspectives on strengths and the case manager relationship. *Soc Work*. 2001;46(3):278-288.

18. Bradford JB, Coleman S, Cunningham W. HIV System Navigation: an emerging model to improve HIV care access. *AIDS Patient Care STDS*. 2007;21(suppl 1):S49-S58.

19. Miller WR, Rollnick S. *Motivational Interviewing: Helping People Change*. 3rd ed. New York, NY: Guilford Press; 2012.

20. Reynolds NR, Sun J, Nagaraja HN, Gifford AL, Wu AW, Chesney MA. Optimizing measurement of self-reported adherence with the ACTG Adherence Questionnaire: a cross-protocol analysis. *J Acquir Immune Defic Syndr*. 2007;46(4):402-409.

21. HIV/AIDS Treatment Adherence, Health Outcomes and Cost Study Group. The HIV/AIDS Treatment Adherence, Health Outcomes and Cost Study: conceptual foundations and overview. *AIDS Care*. 2004;16(suppl 1):S6-S21.

22. National Institutes of Health/National Institute on Drug Abuse. Seek, test, treat and retain: addressing HIV among vulnerable populations. http://www.drugabuse.gov/researchers/research-resources/data-harmonization-projects/seek-test-treat-retain/addressing-hiv-among-vulnerable-populations. Accessed January 23, 2016.

23. McLellan AT, Luborsky L, Woody GE, O'Brien CP. An improved diagnostic evaluation instrument for substance abuse patients: the Addiction Severity Index. *J Nerv Ment Dis*. 1980;168(1):26-33.

24. McLellan AT, Kushner H, Metzger D, et al. The Fifth Edition of the Addiction Severity Index. *J Subst Abuse Treat*. 1992;9(3):199-213.

25. Yudko E, Lozhkina O, Fouts A. A comprehensive review of the psychometric properties of the Drug Abuse Screening Test. *J Subst Abuse Treat*. 2007;32(2):189-198.

26. Kitchens JM. Does this patient have an alcohol problem? *JAMA*. 1994;272(22):1782-1787.

27. Dennis M, Titus J, White M, Unsicker J, Hodkgins D. Global Appraisal of Individual Needs (GAIN): Administration Guide for the GAIN and Related Measures. Bloomington, IL: Chestnut Health Systems; 2008.

28. Riley BB, Conrad KJ, Bezruczko N, Dennis ML. Relative precision, efficiency and construct validity of different starting and stopping rules for a computerized adaptive test: The GAIN substance problem scale. J Appl Measur. 2007;8(1);48-64.

29. Kalokhe AS, Paranjape A, Bell CE, et al. Intimate partner violence among HIV-infected crack cocaine users. *AIDS Patient Care STDS*. 2012;26(4):234-240.

30. Recklitis CJ, Parsons SK, Shih MC, Mertens A, Robison LL, Zeltzer L. Factor structure of the brief symptom inventory—18 in adult survivors of childhood cancer: results from the childhood cancer survivor study. *Psychol Assess*. 2006;18(1):22-32.

31. Derogatis LR. *Brief Symptom Inventory (BSI) 18: Administration, Scoring, and Procedures Manual*. 3rd ed. Minneapolis, MN: National Computer Systems; 2000.

32. Westfall PH, Tobias RD, Wolfinger RD. *Multiple Comparisons and Multiple Tests Using SAS*. SAS Institute Inc; 2011.

33. Meditz AL, MaWhinney S, Allshouse A, et al. Sex, race, and geographic region influence clinical outcomes following primary HIV-1 infection. *J Infect Dis*. 2011;203(4):442-451.

34. Dasgupta S, Oster AM, Li J, Hall HI. Disparities in Consistent Retention in HIV Care—11 States and the District of Columbia, 2011-2013. *MMWR Morb Mortal Wkly Rep*. 2016;65(4):77-82.

35. Colasanti J, Kelly J, Pennisi E, et al. Continuous Retention and Viral Suppression Provide Further Insights Into the HIV Care Continuum Compared to the Cross-sectional HIV Care Cascade. *Clin Infect Dis*. 2016;62(5):648-654.

36. Dennis AM, Napravnik S, Seña AC, Eron JJ. Late entry to HIV care among Latinos compared with non-Latinos in a southeastern US cohort. *Clin Infect Dis*. 2011;53(5):480-487.

37. Rebeiro PF, Gange SJ, Horberg MA, et al; North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD). Geographic variations in retention in care among HIV-infected adults in the United States. *PLoS One*. 2016;11(1):e0146119.

38. Reif S, Pence BW, Hall I, Hu X, Whetten K, Wilson E. HIV Diagnoses, Prevalence and Outcomes in Nine Southern States. *J Community Health*. 2015;40(4):642-651.