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MAJOR ARTICLE

Project RETAIN: Providing Integrated Care for People With HIV Who Use Cocaine

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Background. People with HIV (PWH) who use cocaine are less likely to achieve virologic suppression (<200 copies/mL) because of poor engagement in care. We tested the efficacy of an integrated substance use treatment and outpatient HIV care intervention on improving viral suppression in nonsuppressed PWH who use cocaine.

Methods. Project RETAIN recruited 360 cocaine-using PWH who were not virologically suppressed in Miami, FL, and Atlanta, GA. Patients were randomized to treatment as usual (TAU) or the intervention, which included patient navigation and substance use treatment with motivational enhancement therapy and cognitive-behavioral therapy. The primary outcome assessed viral suppression at 6- and 12-month follow-up.

Results. There was no difference in viral suppression by group (TAU = 17.1%, intervention = 15.6%, $P = .897$). The intervention group had significantly more participation in substance use treatment (87.0%) than TAU (7.2%, $P < .001$). There were significant decreases in stimulant use in both groups, but oxycodone use decreased more in the intervention group. Severe psychological distress (32% of the baseline sample) declined differentially at 6 months (TAU = 24.5%, intervention = 16.1%, $P = .0492$).

Conclusions. Only a minority of PWH who used cocaine became virally suppressed over the 12-month study, with no effect of the integrated intervention. Patients in the intervention did have reduced psychological distress postintervention. Despite more substance use treatment in the intervention, both groups declined equally in substance use. Interventions that improve retention in care and viral suppression are needed for this vulnerable population, including those that address their other complex medical and psychosocial needs.

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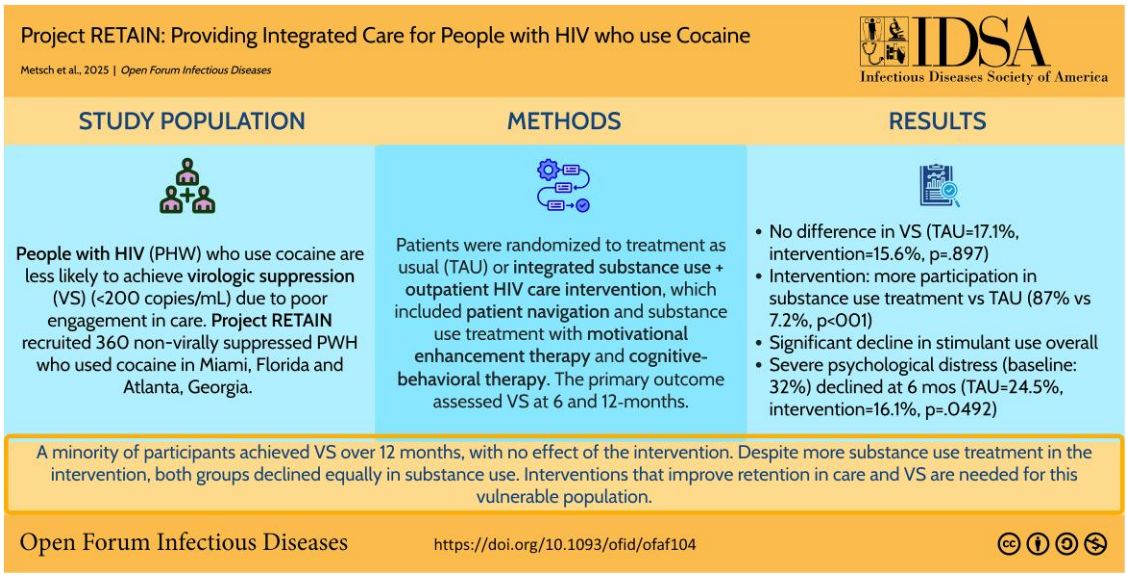
Graphical Abstract



This graphical abstract is also available at Tidbit: https://tidbitapp.io/tidbits/project-retain-providing-integrated-care-for-people-with-hiv-who-use-cocaine-60afd5e4-06dc-438f-bf0b-d60cb456b428?utm_campaign=tidbitlinkshare&utm_source=ITP

Keywords. cocaine use; delivery of health care; HIV; integrated; patient navigation.

Cocaine use has long been associated with risk of acquiring and transmitting HIV infection [1, 2], and crack cocaine specifically has been associated with poor virologic suppression and clinical HIV outcomes [3–5]. For decades, exacerbated stigma and draconian criminal policies have been directed toward the use of "crack cocaine" compared to other drugs [6–8]; the Anti-Drug Abuse Act of 1986 mandated minimum sentences for specified quantities and types of cocaine, whereby the minimum sentence for crack cocaine distribution was equivalent to the minimum sentence for 100 times the quantity of powder cocaine [9]. For persons with HIV (PWH) who use crack cocaine, these structural factors, coupled with lifestyle choices, resulted in marginalization and cumulative disadvantage, often facing poverty, unstable housing, food insecurity, and engaging in harmful relationships because of dependence on others for drugs and income that elevate HIV risk and progression [1, 10, 11]. These negative social forces are often worsened by cooccurring mental health disorders and untreated trauma that further hinder HIV treatment and outcomes [12–18]. Crack cocaine use continues to be prevalent, with almost 1 million U.S. individuals older than age 12 years reporting crack use in the past year; additionally, past-year crack cocaine use among Black people continues to be more prevalent than among other subgroups [19].

There are fewer effective treatments available for stimulant use disorders [20] than for opioid and alcohol use disorders [21–23], and no effective medication assisted treatment for cocaine use [24]. Behavioral treatments such as contingency management (CM) (ie, financial incentives) and cognitive behavioral therapy (CBT) are among the available evidence-based approaches [25, 26], but there has been limited success with integrating such treatments with HIV care [27]. The few efficacious behavioral interventions focused on linking and retaining PWH who use drugs to HIV care have had limited success, particularly in the context of cocaine and crack cocaine use [28]. Recent evidence has shown modest short term effects of CM on viral suppression among PWH who use cocaine, although the sustainability of CM in low-resourced clinics is questionable [29–31].

CBT is an effective and widely used psychological treatment for mental health and/or substance use disorders, including cocaine use [32–34], that utilizes strategies to build coping skills and change an individual's behavioral, emotional, and thinking patterns [35]. By helping patients modify irrational thoughts and negative moods and identify environments that make them prone to relapse, CBT for persons who use drugs has demonstrated efficacy in facilitating continuous abstinence [36, 37] and significantly lengthier periods of self-reported abstinence and treatment retention [36–39]. Notably, CBT's impact on decreasing cocaine use was even more robust among patients with mental health comorbidities [37]. Among PWH, CBT-based interventions show positive HIV-related outcomes, including improved medication adherence and increased CD4 counts, although the sustainability of these benefits over time, especially on discontinuation of the intervention, has been limited [40–43]. Through its patient-centered approach, motivational approaches in conjunction with CBT can encourage persons to engage in HIV care and accept CBT [44, 45].

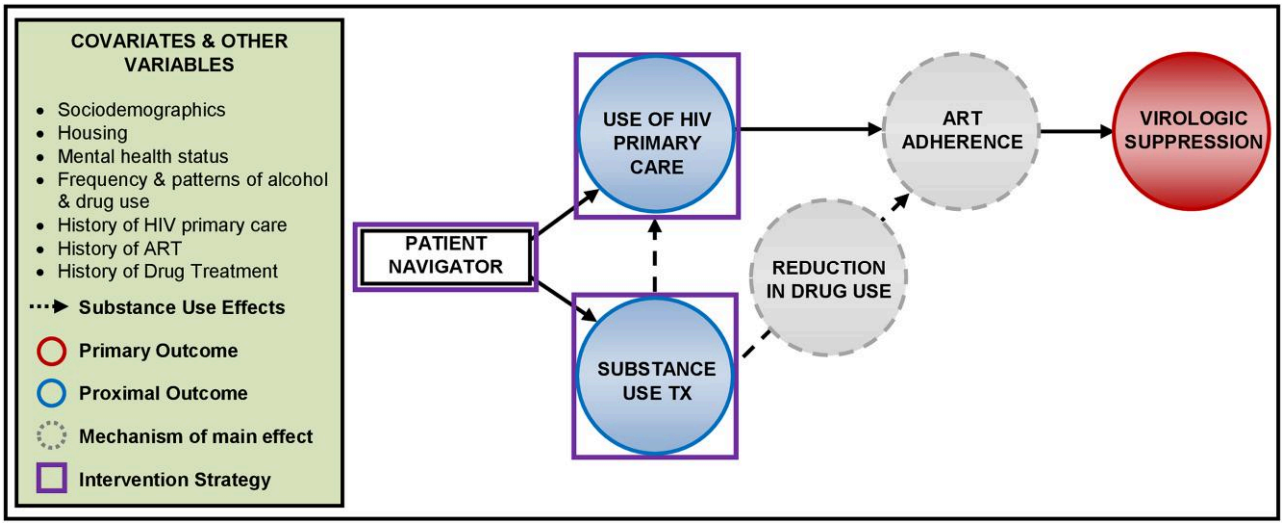


Figure 1. Conceptual model for project RETAIN.

Motivational approach-based studies conducted among marginalized PWH have demonstrated acceptability and feasibility and a positive impact on retention in HIV care, medication adherence, and self-efficacy [44–48]. Similarly, by helping PWH boost their confidence and build problem-solving skills to overcome treatment barriers, patient navigation (PN)-based interventions with PWH have shown favorable outcomes in linking and retaining patients in HIV care [49–52]. However, the impact of PN on entry into HIV care is less pronounced among PWH who use drugs, specifically in the context of cocaine use and lack of drug use treatment [23, 51]. Thus, there is still a great need to develop effective treatments within HIV primary care settings that integrate the complex needs of PWH who use crack cocaine.

Our study "Project RETAIN: Providing Integrated Care for HIV-Infected Cocaine Users" tested a CBT-motivational enhancement therapy (MET) plus PN intervention in HIV care settings to improve HIV viral suppression among PWH who use cocaine. This 2-arm randomized controlled trial (RCT) was conducted in Miami, Florida, and Atlanta, Georgia, regions with some of the highest rates of new HIV diagnoses nationally [53, 54].

METHODS

Participants

Between 2013 and 2016, we prospectively enrolled 360 PWH with detectable viral loads (>200 copies/mL) and recent cocaine use. Participating intervention sites were 2 HIV treatment clinics (Miami, Florida, and Atlanta, Georgia) that had high volumes of patients (>3500 unique outpatients per clinic annually) with prevalent cocaine use. Recruitment occurred in neighboring communities via HIV clinics, medical facilities, and community agencies. Participants were eligible if they (1) were at least 18 years old, (2) were HIV-seropositive (verified via medical record/laboratory results, rapid HIV test with confirmatory test, or viral load), (3) used any cocaine (including crack) in the past 3 months or had a positive toxicology result for cocaine via study toxicology screening, (4) agreed to blood draws for CD4 and viral load testing, (5) reported living in/near Miami or Atlanta and being available for follow-up visits, (6) provided follow-up contact information, (7) could communicate in English, (8) provided written informed consent, (9) signed a Health Insurance Portability and Accountability Act authorization form, (10) were willing to attend study outpatient HIV clinics, and (11) met 1 of the following criteria for HIV: (a) AIDS-defining illness; (b) CD4 cell count <350 cells/μL and a viral load >1000 copies/mL in the medical record in the past 3 months; (c) CD4 cell count <350 cells/μL and a viral load >200 copies/mL via baseline blood draw; or (d) clinical profile indicative of a persistently detectable HIV viral load (>200 copies/mL) attributed to nonadherence to HIV medications per evaluation by a Principal Investigator and/or medical record.

INTERVENTIONS

Conceptual Model

Our conceptual model (Figure 1) theorized the delivery of substance use treatment, CBT/MET over 9 sessions, to be an important mediator for HIV virologic suppression. The model points to the importance of patient navigators in ensuring that intervention patients can access HIV primary care, on-site substance use and mental health counseling, and social services. It also includes covariates theoretically related to the use of HIV or substance use treatment (eg, sociodemographics, prior antiretroviral therapy [ART] use).

Integrated Substance Use/PN Intervention

The intervention incorporated HIV primary care with on-site substance use treatment and hands-on PN assistance. Participants had up to 11 check-ins with a patient navigator (over a 6-month period), some who had a Master of Social Work degree as well as additional training in social work. Participants also had up to 9 sessions with a substance use counselor (over the first 3 months). During check-ins, the patient navigator reviewed the participant's treatment plan, provided informational and motivational/emotional support, reinforced skill-building, and assisted with accessing services. Because having a detectable viral load was part of the study eligibility, these navigators predominantly focused on initiation/reinitiation of ART and transitioned to adherence to ART, depending on each individual patient's needs, capabilities, and willingness to engage in HIV primary care and treatment. The PN approach drew on a strengths-based approach that empowered participants to use their internal strengths, skills, and assets to increase their self-efficacy, overcome barriers, and achieve their behavioral goals [51, 55, 56]. The first 2 substance use treatment sessions made extensive use of MET motivational strategies to focus on readiness for treatment; after achieving motivation, the focus shifted to skill-building [57]. Treatment sessions focused on identifying high-risk situations for substance use, developing effective coping strategies, and altering maladaptive cognitions.

Treatment as Usual

Treatment as usual (TAU) participants received their clinic's standard of care, including primary HIV care, case management, and referral to substance use treatment as needed.

Intervention Fidelity

All intervention sessions were audio recorded with participant consent, and 10% of the recordings were reviewed randomly to provide feedback and ensure high-quality delivery. Ratings were in categories of MET consistent, CBT consistent, MET/CBT inconsistent via a 7-point scale: (adherence: 1 = not at all to 7 = excellent). Because not all CBT items are expected at each session, adherence ratings of 1 are excluded from rating of adherence. There was good consistency in ratings across raters. Kappa for adherence was 0.88 and 0.72 for competence.

Randomization

Randomization was stratified by site and gender equally between groups. Participants randomized to TAU were informed that they would meet with clinic case management staff and be scheduled by study staff for 6- and 12-month study assessments. Participants randomized to the intervention group were informed that they would meet with a patient navigator and substance use counselor and receive care through the intervention.

MEASURES

Outcome assessments were conducted at baseline and at 6- and 12-month follow-up. Self-report measures were administered through audio computer-assisted self-interviewing (ACASI). ACASI is well-accepted in reducing socially desirable responding, including among individuals with low education levels [58, 59]. Additionally, ACASI (vs interviewer-administered surveys) enhances the reporting of sensitive information that may be difficult to disclose for PWH, including sexual practices, history of trauma/violence, and drug use [60–62].

Primary Outcome

The primary study outcome was binary: undetectable (< 200 copies/mL, defined as viral suppression) versus detectable HIV viral load at 6 and 12 months. Intervention efficacy was defined as having an undetectable viral load at both follow-up assessments. In post hoc analyses, we explored partial efficacy, defined as a detectable viral load at only 1 of the 2 follow-ups. Although the goal of therapy for patients on ART is to achieve a viral load "below the limit of detection of the assay" (usually < 50 copies/mL), we chose <200 copies/mL for viral suppression cutoff to avoid small "blips" and episodes of low-level viremia that are not uncommon.

Secondary Outcomes

Attendance at HIV care visits was defined as at least 1 visit to an HIV care provider in the past 6 months. At each follow-up visit, we recorded healthcare utilization information through self-report of recent clinic visits/hospital admissions (and if HIV-related) in the past 6 months to create a composite measure for assessment.

Adherence self-efficacy was assessed with the HIV Adherence Self-Efficacy Scale (HIV-ASES), a 12-item scale of patient confidence to carry out treatment-related behaviors and integrate medication regimens with activities of daily living [63]. Responses range from 1 ("cannot do it at all") to 10 ("certain can do it"). We created 2 subscales of the HIV-ASES, Integration and Perseverance, to decompose significant impacts on adherence self-efficacy [63] at baseline and both follow-up visits.

Psychological distress was measured using the Center for Epidemiological Studies-Depression scale [64] with a cutoff of 27 [65] to indicate severe levels of psychological distress likely associated with diagnostic criteria for major depressive disorder.

Entry and attendance at substance use treatment were assessed by self-report in both study groups, as well as any additional nonstudy-related substance use treatment attendance by intervention study participants.

Frequency and pattern of alcohol and substance use in the past 30 days was measured using the 10-item Alcohol Use

Disorders Identification Test (AUDIT) [66, 67], drug use matrix used in National Institute on Drug Abuse Clinical Trials Network studies [68], and Drug Abuse Screening Test (DAST-10) to document the severity of current substance use [69, 70]. Specific drugs used were assessed through urine drug testing at baseline and both follow-ups.

Other Measures

Verification of self-report: We retrospectively abstracted information from participants' medical records, including number of primary care visits during the 12-month study period and reason for visit, CD4 count and viral load, HIV treatment regimen, and presence of opportunistic infections.

Statistical Analysis

Baseline characteristics were compared between groups using contingency tables and *t*-tests to assess equivalence as a result of randomization. For the primary and secondary outcomes at 6 and 12 months, we used repeated measures models using generalized estimating equations [71] that adjusts for the clustering that arises from correlated data within each participant. A particular strength of generalized estimating equations is their robustness to misspecification of within subject error, and they are robust for data missing completely at random. All hypotheses were tested using 2-sided tests at $\alpha = 0.05$. An intent-to-treat analysis was performed (ie, group assignment was used as the basis of comparison). We adjusted for potential differences between study sites by including study site as a blocking variable in multivariable analyses.

RESULTS

We recruited and screened 821 patients in Atlanta and Miami. After screening, 461 were ineligible and excluded (Figure 2) and 360 were randomized (of which ~60% were in Miami) (Table 1). There was no significant difference between the 2 randomized groups based on sociodemographics or HIV-related outcomes. The majority were male (63.4%) and Black (83.6%) with most being high school graduates or less (83.6%). About 91% reported ever being in jail/prison and 85.6% had a positive urine drug test at baseline. All participants self-reported use of cocaine and 85% reported use of crack cocaine at baseline. Only 5.4% were employed and 5.9% had incomes greater than $10 000. More than one third were housing insecure (36.2%). Almost one third (31.1%) experienced severe psychological distress and virtually all participants (98.7%) had detectable HIV-1 viral loads at baseline.

Primary Outcome

There were no differences in viral suppression rates between the 2 groups (Table 2); the proportion of participants achieving intervention efficacy (ie, viral suppression at both 6 and 12 months) were 17.1% for TAU and 15.6% for the intervention. Viral suppression at 6 months was 27.6% and 27.9%, and at 12 months 32.0% and 33.0%, in TAU and intervention, respectively. Viral load and CD4 both significantly improved at 6 and 12 months compared to baseline for both groups. There were no differences between the 2 groups or treatment and time interactions.

Secondary Outcomes

Attendance at HIV Care Visits. At baseline, about 30% of participants in each group reported having attended an HIV-related visit during the past 6 months. Although this number slightly increased to 40% in TAU and 45.5% in the intervention at 12-month follow-up, there was no statistical change in HIV care attendance at 6 and 12 months. Significant differences in the number of HIV care visits between the treatment groups across times were observed ($P = .0166$), indicating more visits in the intervention condition compared to TAU. There was not a significant time by treatment interaction effect.

Adherence Self-efficacy. There was no significant difference in adherence to HIV treatment regimens by group. However, there was a significant increase in HIV medication taken in the past month across groups at both 6 and 12 months.

Entry and Attendance at Substance Use Treatment. There was a statistically significant difference in the proportion of participants receiving substance abuse treatment by treatment group ($P = .0001$) at different times ($P = .0002$). The differences over time differed by treatment group ($P = .0001$), driven by the receipt of substance use treatment in the intervention group between baseline and 6 months (87.0%) relative to in the control group (7.2%).

Severe Psychological Distress. More than 30% of the sample showed severe psychological distress at baseline. There were significant declines in distress over time ($P = .0001$). Whereas the time-by-treatment interaction was not statistically significant ($P = .1178$), there was a statistically significant difference at 6 months ($P = .0492$) with 24.5% in TAU and 16.1% in the intervention experiencing severe psychological distress.

Substance Use. There was no significant difference in AUDIT or DAST-10 scores, nor in urine toxicology screenings, by group. However, within both groups, there were significant decreases in AUDIT and DAST-10 scores, as well in use of stimulants, cocaine, and tetrahydrocannabinol, at follow-up compared to baseline. In addition, a significant interaction effect ($P = .0436$) was observed, suggesting differences in oxycodone use between groups over time. Particularly, oxycodone use decreased more significantly in the intervention group, especially by 12 months.

Intervention Duration and Fidelity. The intervention was 6 months in duration and included up to 11 sessions of

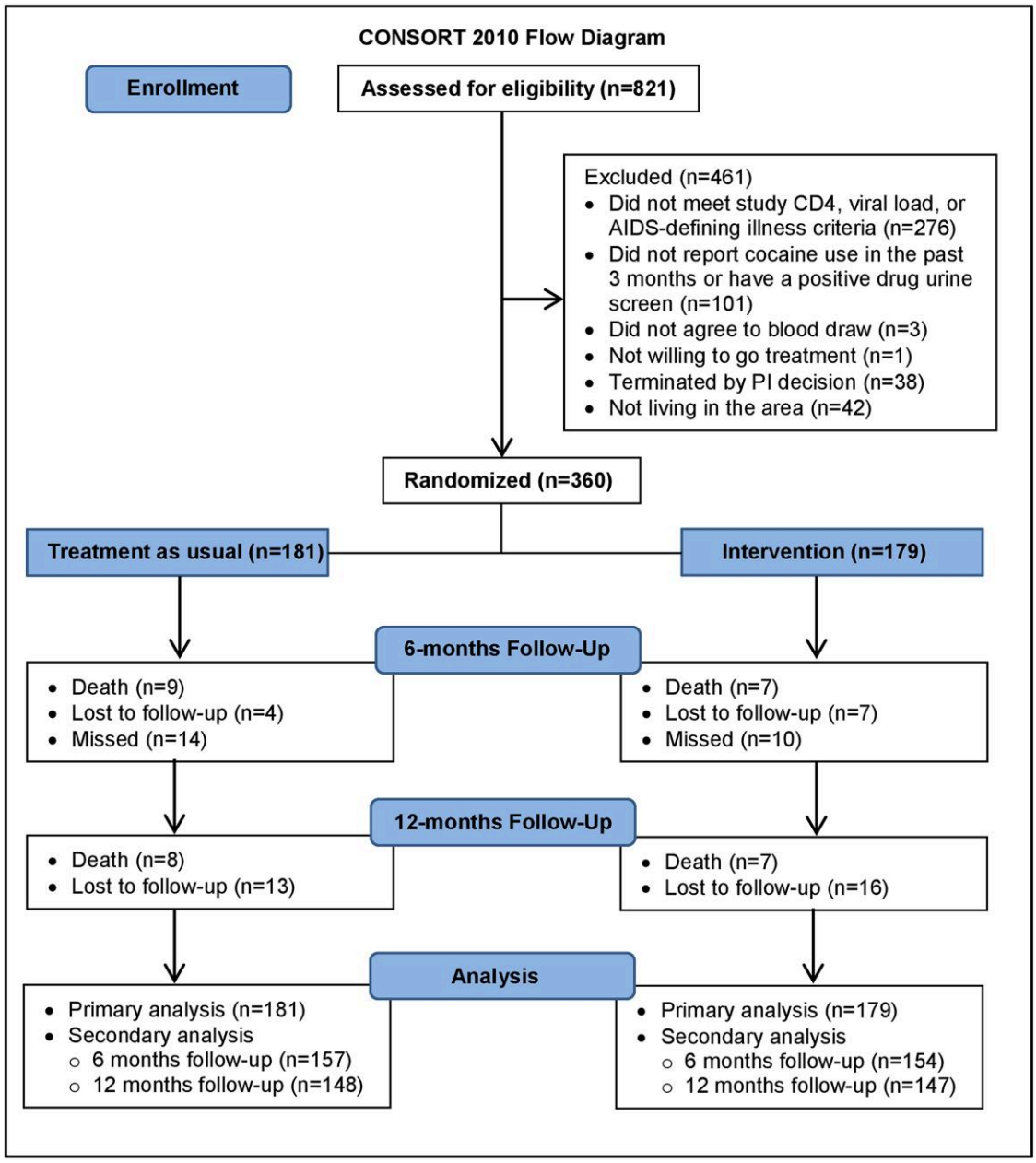


Figure 2. CONSORT flow diagram for project RETAIN.

strengths-based PN (maximum 1 hour each). During the first 3 months of the intervention, participants received up to 9 sessions of substance use treatment (1 hour each). Mean adherence ratings were 3.4 and 4.1 for MET and CBT consistent items, respectively. Mean competence ratings were 4.9 and 5.0 for MET and CBT consistent items, respectively. For MET/CBT inconsistent items, mean ratings were 1.9 and 3.6 for adherence and competence ratings, respectively. More than 58% of intervention participants received 5 or more substance abuse treatment sessions and more than 80% received 5 or more PN sessions.

DISCUSSION

Study findings contribute to the field of HIV engagement in care and substance use research, as the extant literature testing integrated substance use treatment and HIV care on viral suppression has been limited [72]. The small number of RCTs with positive results on integrated HIV care and substance use treatment have focused on PWH and opioid use and specifically focused on integrated buprenorphine and HIV care [21, 73, 74]. Furthermore, very few studies have conducted RCTs with a population of people with uncontrolled HIV infection and substance use.

Table 1. Demographic and HIV Care at Baseline, by Study Arm

	TAU (n = 181)	Intervention (n = 179)	Overall (n = 360)
City			
Atlanta	72 (39.8)	72 (40.2)	144 (40)
Miami	109 (60.2)	107 (59.8)	216 (60)
Gender			
Male	114 (63.7)	113 (63.1)	227 (63.4)
Female	65 (36.3)	66 (36.9)	131 (36.6)
Race/ethnicity			
White	8 (4.5)	8 (4.5)	16 (4.5)
Black	144 (81.8)	151 (85.3)	295 (83.6)
Hispanic	18 (10.2)	14 (7.9)	32 (9.1)
Other	6 (3.4)	4 (2.3)	10 (2.8)
Education			
High school graduate or less	151 (85.8)	145 (81.5)	296 (83.6)
Some college or more	25 (14.2)	33 (18.5)	58 (16.4)
Ever in jail or prison	159 (90.3)	163 (91.6)	322 (91)
Jail or prison in the last 6 mo	34 (19.3)	33 (18.5)	67 (18.9)
Employment status			
Full- or part-time work	7 (4)	12 (6.7)	19 (5.4)
Disabled or retired	100 (56.8)	99 (55.6)	199 (56.2)
Looking for work, student, other	69 (39.2)	67 (37.6)	136 (38.4)
Marital status			
Married,	8 (4.8)	10 (6.3)	18 (5.6)
Widowed, divorced, separated	18 (10.9)	14 (8.8)	32 (9.9)
Never married	139 (84.2)	135 (84.9)	274 (84.6)
Income (>$10k)	7 (4)	14 (7.9)	21 (5.9)
DAST-10 score (≥6)	44 (24.6)	44 (25.1)	88 (24.9)
House insecure	63 (34.8)	67 (37.6)	130 (36.2)
Food insecure	10 (5.8)	10 (5.8)	20 (5.8)
CESD (≥16)	111 (62.7)	109 (63)	220 (62.9)
Any positive urine drug test	144 (83.2)	148 (88.1)	292 (85.6)
Stimulants (methamphetamine + cocaine + amphetamine)	125 (72.3)	125 (74.4)	250 (73.3)
Methadone or buprenorphine	8 (4.6)	10 (6.0)	18 (5.3)
Cocaine	124 (71.7)	122 (72.6)	246 (72.1)
Benzodiazepine	54 (31.2)	40 (23.8)	94 (27.6)
Cannabis	72 (41.6)	72 (42.9)	144 (42.2)
Opioids	23 (13.3)	15 (8.9)	38 (11.1)
Any HIV doctor visit (past 6 mo)	53 (29.6)	53 (30.5)	106 (30)
Viral suppression	3 (1.7)	2 (1.1)	5 (1.4)
Substance use treatment visit (past 6 mo)	15 (8.6)	17 (9.8)	32 (9.2)
Fisher test for cell with value <5.			

Abbreviations: CESD, Center for Epidemiological Studies Depression scale; DAST-10, Drug Abuse Screening Test; TAU, treatment as usual.

Project RETAIN study findings showed no effect of the intervention on the primary and secondary outcomes, except the intervention group received more substance use treatment and was positively associated with decreases in depression and oxycodone use. It is important to recognize that the Project RETAIN intervention was evaluated as a priori primary outcome of viral suppression at both follow-up assessments, an ambitious goal. However, there was no effect at either outcome assessment, with approximately one third of participants overall being virally suppressed at 6 and 12 months. Study results show that the majority of participants in both groups continued to have detectable viral loads, despite the intervention participants having received evidence-based PN and substance use treatment.

It is helpful to compare these negative study results to our previous RCT, CTN0049/Project HOPE [75], which demonstrated the efficacy of PN + CM with 801 hospitalized PWH who used opioids, stimulants, and/or heavy alcohol in achieving viral suppression after completion of the intervention at the 6-month follow-up (compared to PN alone and TAU). Specifically, the CTN0049 study showed that almost half the participants (46.2%) in the PN + CM group were virally suppressed, versus 35.2% of TAU ($P = .04$). Notably, the majority of CTN0049 participants used stimulants (70.8%). Although the effect dissipated 6 months after the intervention completed with a negative effect finding at the 12-month follow-up assessment (which was the a priori outcome), CTN0049 had more short-term success than the current study. This may be due to several key features of Project RETAIN.

Project RETAIN enrolled participants who were using (or recently used) cocaine, living with detectable HIV viral loads. The CBT/MET and PN intervention required participants to attend multiple sessions—likely an unrealistic expectation for this population with complex medical and psychosocial needs. We know that CBT-informed interventions have worked with other populations in achieving HIV outcomes [40, 41], and it is possible that offering different intervention methodologies, such as digital formats or drop-in centers, may show more positive results. For example, Glassner and colleagues' text-based CBT intervention pilot study [27] showed preliminary efficacy in improving HIV medication adherence and viral load for PWH and opioid and stimulant use disorders. Another predetermined approach to multiple in-person sessions, in terms of timing and duration, could be open-access drop-in centers that participants can access when their schedules align [76].

Additionally, cocaine, and crack cocaine in particular, has been associated with suboptimal HIV prevention and treatment outcomes since the beginning of the epidemic. Early studies focused on condom use and sexual risk reduction with persons who used crack cocaine were unsuccessful in preventing HIV acquisition and transmission [77–79]. There are currently no medications for persons with cocaine use and the limited studies to date that have increased viral suppression for PWH have involved medications for opioid use disorders [21]. The CTN0049 study's successful HIV outcomes at 6 months employed CM; research suggests that CM works better than CBT for cocaine users [80]. Furthermore, HIV medications have improved considerably in the past few years with increased efficacy, fewer side effects, and reduced dosing [81–83]; the advent of long-acting injectable ART [84, 85], alongside evidence-based substance use treatment, could lead to better

Table 2. Primary and Secondary Outcomes, by Study Arm and Time

	Baseline		6 M		12 M		*P Values*		
	TAU (N = 181)	Intervention (N = 179)	TAU (N = 157)	Intervention (N = 154)	TAU (N = 148)	Intervention (N = 147)	TAU versus Intervention	Time	Interaction
Primary Outcomes (n (%) or mean (SD))									
Viral suppression at 6 and 12 mo					31/181 (17.1)	28/179 (15.6)	.8851		
Viral suppression	3/181 (1.7)	2/179 (0.6)	50/181 (27.6)	50/179 (27.9)	58/181 (32.0)	59/179 (33.0)	.7756	<.0001	.8769
Log10 (VL)	10.15 (2.22)	10.06 (2.14)	7.8 (3.51)	7.62 (3.46)	7.1 (3.41)	7.24 (3.55)	.6972	<.0001	.7228
CD4 count, cells/μL	191.6 (170.3)	174.0 (132.5)	252.1 (205.2)	227.1 (180.9)	273.7 (223.0)	234.1 (213.2)	.1306	<.0001	.7679
Secondary outcomes									
Attendance to HIV care visits									
Any doctor visit	64/179 (35.8)	59/174 (33.9)	57/150 (38)	64/149 (43)	57/143 (39.9)	61/134 (45.5)	.4052	.1207	.5392
Any HIV visit	53/179 (29.6)	53/174 (30.5)	46/150 (30.7)	55/149 (36.9)	41/143 (28.7)	50/134 (37.3)	.0981	.5411	.512
N of doctor visits	0.7 (1.6)	0.7 (1.8)	0.6 (1.2)	1 (2.4)	0.7 (1.5)	0.7 (1.3)	.2283	.6424	.3711
N of HIV visits	0.5 (1.1)	0.6 (1.7)	0.5 (1)	0.9 (2.4)	0.5 (1.3)	0.7 (1.8)	.0166	.7085	.6514
Adherence to HIV treatment regimens									
Any missed	77/101 (76.2)	89/108 (82.4)	65/111 (58.6)	58/119 (48.7)	53/118 (44.9)	57/116 (49.1)	.0981	.5411	.512
% medication taken	82.9 (32.7)	87 (24.6)	85 (28)	88.7 (24.4)	93.7 (17.6)	93.6 (16.6)	.3101	<.0001	.0235
HIV-ASES	77 (31.3)	82.5 (27.2)	92 (30.5)	97.2 (21.9)	100.8 (23.1)	95.7 (25.3)	.3221	<.0001	.0246
HIV-ASES-Integration	58.1 (24.3)	62 (20.1)	68.8 (23.7)	73 (16.3)	75.8 (17.3)	71.9 (19)	.3853	<.0001	.0591
HIV-ASES-Perseverance	19.3 (7.9)	20.5 (7.6)	23.2 (7.4)	24.3 (5.8)	25.2 (5.9)	24 (6.6)	.3101	<.0001	.0235
Severe psychological distress	55/177 (31.1)	57/173 (33.0)	37/151 (24.5)	24/149 (16.1)	19/143 (13.3)	19/134 (14.2)	.4068	0.0001	0.1178
Attendance at substance use treatment									
Any outpatient	6/175 (3.4)	3/172 (1.7)	7/144 (4.9)	122/141 (86.5)	4/135 (3)	2/129 (1.6)	.1013	.0265	.0137
Any residential	14/175 (8)	16/174 (9.2)	11/149 (7.4)	14/146 (9.6)	9/136 (6.6)	9/131 (6.9)	.5295	.6541	.9235
Any treatment	15/175 (8.6)	17/174 (9.8)	16/149 (10.7)	127/146 (87.0)	10/139 (7.2)	14/131 (10.7)	.0001	.0002	.0001
Substance use									
Any drug use	144/173 (83.2)	148/168 (88.1)	108/149 (72.5)	115/150 (76.7)	97/140 (69.3)	87/138 (63)	.5712	<.0001	.1891
AUDIT (>3)	80/179 (44.7)	90/175 (51.4)	56/148 (37.8)	48/148 (32.4)	38/140 (27.1)	40/132 (30.3)	.6256	<.0001	.1704
DAST (>3)	83/179 (46.4)	87/175 (49.7)	24/148 (16.2)	31/149 (20.8)	16/141 (11.3)	26/132 (19.7)	.0542	<.0001	0.4772
DAST (>6)	44/179 (24.6)	44/175 (25.1)	9/148 (6.1)	15/149 (10.1)	9/141 (6.4)	13/132 (9.8)	.1605	<.0001	.4637
Urine drug screen									
Stimulants	125/173 (72.3)	125/168 (74.4)	82/149 (55)	73/150 (48.7)	65/140 (46.4)	61/138 (44.2)	.6171	<.0001	.5634
Cocaine	124/173 (71.7)	122/168 (72.6)	79/149 (53)	72/150 (48)	63/140 (45)	58/138 (42)	.5445	<.0001	.7976
Benzodiazepines	54/173 (31.2)	40/168 (23.8)	36/149 (24.2)	37/150 (24.7)	33/140 (23.6)	33/138 (23.9)	.5136	.5025	.4079
THC (marijuana, etc.)	72/173 (41.6)	72/168 (42.9)	41/149 (27.5)	51/150 (34)	41/140 (29.3)	37/138 (26.8)	.7059	.0002	.3617
Opioids	23/173 (13.3)	15/168 (8.9)	14/149 (9.4)	8/150 (5.3)	12/140 (8.6)	14/138 (10.1)	.2663	.1627	.2578

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; DAST, Drug Abuse Screening Test; HIV-ASES, HIV Adherence Self-Efficacy Scale; SD, standard deviation; TAU, treatment as usual; VL, viral load.

outcomes in future studies. However, there are considerable challenges to be addressed before HIV clinics can systematically offer these treatment advances to vulnerable patients with complex needs [86].

It is also possible that a stronger focus on HIV treatment adherence—as opposed to our intervention's integrated PN/substance use treatment approach, concurrently focused on reducing substance use—may have resulted in increased HIV viral suppression. Future studies may also want to consider a harm reduction approach toward substance use, where the focus is not on abstinence and treatment but rather on developing strategies to reduce harms related to substance use, with the primary goal of ART treatment adherence and achievement of HIV viral suppression [87].

There are likely social forces that our participants faced that are more powerful than behavioral interventions in shaping their opportunities and lifestyles. These include structural and systemic factors that contribute to their cumulative social disadvantage, including poverty, unstable housing, unemployment, and mass incarceration. This study documented high rates of depression, and the intervention may have been stronger had we more fully addressed mood and other psychiatric disorders. Notably, we did observe a positive effect of the intervention in reducing depression as well as oxycodone use. These positive findings likely speak to the psychosocial–emotional support offered in the CBT/MET and PN intervention.

Some limitations should be noted. First, although most of the intervention participants attended at least some of the study sessions with high rates of intervention fidelity and follow-up, a sizeable minority did not attend the full intervention, which could hinder intervention evaluation. Second, the study design does not allow for understanding the separate effects of the CBT/MET and PN intervention components. Finally, although the primary outcome was biologic, there was some reliance on self-report for secondary outcomes, including substance use treatment attendance outside of the intervention.

Despite these limitations, this study is one of few enrolling a near total sample who reported substance use, prior jail time, and unsuppressed viremia. To achieve the national goal of ending the HIV epidemic, we must continue to test strategies to achieve viral suppression in hard-to-engage vulnerable populations who have been left behind in the advances of HIV treatment. Our negative trial findings suggest that new and novel approaches are needed, such as integrating long acting injectable ART with substance use treatment, better addressing structural and systemic factors, and/or delivering different intervention formats.

Notes

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Patient consent statement. This study was approved by the University of Miami, Columbia University, and Emory University institutional review boards. All participants provided informed consent before study participation.

Potential conflicts of interest. There are no conflicts of interest to report.

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