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The CARES Program: Improving Viral Suppression and Retention in Care Through a Comprehensive Team-Based Approach to Care for People with HIV and Complex Psychosocial Needs

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Abstract

Retention in HIV care and viral suppression rates remain suboptimal, especially among people with HIV (PWH) facing complex barriers to care such as mental health conditions, substance use disorders, and housing insecurity. The Center for Adherence, Retention, and Engagement Support (CARES) program utilizes an interdisciplinary team that delivers integrated services in a drop-in setting to provide individualized care to PWH with complex psychosocial needs. We describe the CARES program and evaluate its effectiveness in retaining patients in care to achieve virological suppression. We characterized 119 referrals of PWH experiencing homelessness, mental health conditions, and substance use disorders to CARES between 2011 and 2017, and collected data for a 24-month observation period through 2019. Outcomes of patients who participated in CARES were compared with those who were referred but did not participate. The primary outcome was viral suppression (<200 copies/mL) at least once during 2-year follow-up. Retention in care (≥ 2 completed medical visits ≥ 90 days apart in each year post-referral) was a secondary outcome. Of 119 PWH referred to CARES, 59 participated with ≥ 2 visits. Those who participated in CARES were more likely to achieve viral suppression [adjusted odds ratio (aOR) 3.50, 95% confidence interval (CI) 1.19–10.32] and to be retained in care (aOR 3.73, 95% CI 1.52–9.14) compared with those who were referred but did not participate. This analysis found that the CARES program improved retention in care and viral suppression among PWH with complex psychosocial needs and suggests that it may represent a useful model for future programming.

Keywords: HIV care continuum, substance use, mental health, housing insecurity, retention in care

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Introduction

AN ESTIMATED 1.1 million adults and adolescents are living with HIV in the United States, with 30,635 new infections in 2020.¹ Despite advances in antiretroviral therapy (ART), mortality, and morbidity—both from opportunistic infections and from noncommunicable diseases—remain unacceptably high among people with HIV (PWH).^{2,3} In addition, HIV transmission rates have remained stable for the past several years.^{4–8} For mortality and transmission rates to further decline, a greater percentage of PWH need to achieve and maintain viral suppression. This requires individuals to be effectively engaged at every point along the HIV care continuum.⁹

The National HIV Strategy for the United States (NHAS) recognizes that closing gaps at every step of the HIV care continuum is a priority, both to improve health for PWH and to prevent new infections.¹⁰ NHAS goals include increasing the percentage of newly diagnosed PWH who are retained in HIV care to 90%, and increasing the percentage of persons with diagnosed HIV infection who are virally suppressed to 80%. At present, engagement in the HIV care continuum is comparatively low: it is estimated that only 49% of PWH have been retained in care, and only 53% have achieved viral suppression.⁹

Suboptimal retention in care largely reflects the numerous economic, social, and structural barriers faced by PWH.^{11–15} PWH who are homeless, have substance use disorders, or have psychiatric illness have especially low rates of retention in care, as well as worse health outcomes.^{16–18} A variety of interventions have been tested to increase retention in HIV care.¹⁹ Motivational interviewing, adherence counseling, and HIV education alone do not appear to improve retention in care, but interventions such as enhanced personal contact and clinic-based substance use disorder treatment have both been associated with improved retention.^{19–21}

Interventions focused solely on increased outreach have not been associated with increased viral suppression among PWH who are disengaged from care.^{22,23} However, more comprehensive programs—such as those that include enhanced case management and care coordination with linkage to a suite of medical and nonmedical resources—have shown promise in promoting retention in care and viral suppression, suggesting that intensive programming may be required to support retention in care for those with more complex needs.^{20,24–26}

The Center for Adherence, Retention, and Engagement Support (CARES) was established as an integrated care specialty program within a large urban HIV primary care center. The goal of CARES was to optimize the physical, emotional, and spiritual health and well-being for a population of PWH with psychosocial complexities posing substantial barriers to primary care retention and viral suppression, including housing insecurity, serious mental health conditions, and substance use disorders. In this article, we describe the CARES program and evaluate its effectiveness in retaining patients in the HIV care continuum and achieving virological suppression.

Methods

Study setting and population

All patients were enrolled in the Ponce de Leon Center (Ponce Center) of the Grady Health System in Atlanta, Georgia. The Ponce Center is an urban Ryan White

HIV/AIDS Program-funded clinic serving >6000 un- or underinsured patients.¹⁴ The majority of Ponce Center patients have a history of AIDS. Those without an AIDS diagnosis were either ≤ 24 years of age, pregnant, had severe mental health or substance use disorders, or had complicating medical comorbidities requiring subspecialty care at the time of Ponce Center enrollment. Patients were referred to the CARES program by Ponce Center primary care providers in accordance with the following referral criteria: age ≥ 18 years, history of serious mental health conditions, severe substance use disorders, homelessness, and/or other psychosocial conditions impeding access, medication adherence, or retention in HIV care. The program was advertised internally (e.g., at routine meetings) to referring Ponce Center HIV primary care providers but was not externally advertised.

Intervention components

The CARES program employed an interdisciplinary team to provide individualized care to patients with complex psychosocial needs utilizing an integrated care model. Key components of the CARES model included a flexible open-access design without need for appointments; individualized adaptations; a multi-disciplinary team approach with consistent availability of full-time staff; and a centralized, welcoming, supportive, and secure location allowing for the creation of a community identity. Further, the CARES program did not require sobriety or 100% adherence for patients to attend.

Services were delivered by a core clinical team comprising a registered nurse, psychiatric nurse practitioner, case manager, chaplain, and certified medical assistant. Services included medication adherence support (including directly observed ART administration), health system navigation, health education, group and individual psychotherapy, psychiatric medication management, intensive case management (e.g., needs assessments, navigation of medical and support services, community resource referrals, and legal assistance referrals), and spiritual guidance and support. On-site meal packets were provided through a partnership with a local food pantry and refreshments were available for individuals presenting for CARES services.

Study design and variables

A retrospective chart review of 119 patients referred to the CARES program between June 2011 and April 2017 was performed, with data collected extending through April 2019 to include 24 months of observation. Variables were manually abstracted from the electronic health record (EHR). Missing data were supplemented by data obtained from the Center for AIDS Research (CFAR) HIV Disease Registry. The Registry contains data from the EHR for patients who received care in the Grady Health System. The study was approved by the Emory University Institutional Review Board. Informed consent was waived. Data collected contained protected health information and were accessed on encrypted computers on an Emory or Grady VPN and stored on Emory's HIPAA-compliant Box storage platform in password-protected worksheets.

For the exposure variable, patients were classified as participating in CARES if they had ≥ 2 visits in the CARES program, defined as nursing visits, group psychotherapy visits, or individual behavioral health care visits. Patients

referred into CARES who had one visit or no visits within the CARES program were categorized as referred but not participating and were used as the control group. All patients referred to CARES during this time were included in the analysis, regardless of whether they remained actively engaged in the clinic at 2 years of follow-up.

Covariates abstracted from the EMR included age, gender, race, education level, residential status, substance use, psychiatric comorbidities, and baseline plasma HIV-1 RNA viral load (VL) and CD4+ T cell count. Residential status was categorized as stably housed or homeless. Substance use was classified as current use or active treatment; prior use; or no use of cocaine, alcohol, marijuana, and/or methamphetamines. Psychiatric diagnoses were separated into depressive and anxiety disorders, psychotic disorders, bipolar-type disorders, or post-traumatic stress disorder. Baseline CD4 count and VL were defined as the most recent measures before referral or the first recorded after referral. Baseline retention was defined as having completed at least two HIV medical care encounters (either two visits with a provider or one visit with a provider and one VL measurement) separated by >90 days in the year before referral.

For the primary outcome, viral suppression, defined as a VL <200 copies/mL at least once within 2 years after referral, was compared between patients who participated in CARES versus those who were referred but did not participate. Using an intention-to-treat analysis, all missing VLs were considered not suppressed. Retention in care, which was defined as having had at least two HIV medical care encounters (either two visits with a provider or one visit with a provider and one laboratory visit with VL measurement) separated by >90 days in each year of the 24-month observation period, was compared between the two groups as a secondary outcome.

Statistical analyses

Descriptive statistics for continuous variables included the mean and standard deviation. Categorical variables were summarized using frequency counts and percentages. These statistics were calculated for patients who participated in CARES versus patients who were referred but did not participate.

Baseline continuous characteristics were compared between study groups using the Wilcoxon rank-sum test and baseline categorical characteristics were compared between study groups using a chi-square test or Fisher's exact test.

Viral suppression rates and retention in care rates were compared between the group of patients who participated in CARES and the group of patients who did not participate using a chi-square test or Fisher's exact test. Univariate logistic regression was performed to identify variables associated with the outcomes of interest. Variables that were significantly associated with the outcomes of interest ($p < 0.2$) in univariate analysis were incorporated into a multi-variate model. p Values <0.05 were considered statistically significant. All analyses were performed with Stata version 13.1 (StataCorp, College Station, TX, USA).

Results

Descriptive statistics for 119 patients referred to the CARES program between 2011 and 2017 are provided in Table 1. As compared with the general clinic population re-

ceiving care at the Ponce Center, the total cohort was similar with regard to age and gender, but more likely to identify as African American (90.8% vs. 79.7%) and less likely to have stable housing (35.3% vs. 87.7%). Of those who were referred, 59 participated in CARES with two or more visits. At baseline, the median age of patients who participated in CARES was 50 years, compared with 46.5 years for patients who were referred but did not participate ($p = 0.02$).

Ninety percent of all patients identified as African American, 7.6% as White, and 1.7% as Hispanic. Patients experiencing homelessness accounted for 64.7% of the total cohort. Patients in the participant group were not significantly different from those in the referred but not participating group with regard to gender, race, homelessness, education, and substance use. There were significantly more patients with diagnoses of depression or anxiety among those who participated in CARES versus those who did not participate (52.5% and 25.0%, respectively; $p = 0.002$).

Baseline HIV-related characteristics were not statistically different between groups. Median baseline VL was 4.17 for CARES participants and 4.11 for those who did not participate (\log_{10} copies/mL, $p = 0.36$). At baseline, 23.7% of CARES participants had achieved viral suppression, as compared with 28.3% of those who did not participate ($p = 0.68$). Median baseline CD4 count was 143 cells/ μ L for CARES participants and 185.5 cells/ μ L for those who did not participate, and this difference was not statistically significant ($p = 0.35$). In the year before referral, 39.0% of CARES participants and 48.3% of those who did not participate had attended two or more HIV medical care visits separated by at least 90 days ($p = 0.36$).

Of patients who participated in CARES, 89.8% achieved viral suppression (VL \leq 200 copies/mL) at least once during the 24 months of observation, as compared with 75.0% of patients who did not participate ($p = 0.034$; Table 2). All patients who had achieved viral suppression at baseline were able to achieve viral suppression at least once during the 24 months of observation whether or not they participated in CARES. Among those who were not virally suppressed at baseline, 86.7% of those who participated in CARES achieved viral suppression at least once during the 24 months of observation, as compared with 65.1% of those who did not participate ($p = 0.018$).

Retention in care was significantly different between the two groups: 74.6% of those who participated in CARES were retained in care throughout the 24 months of observation as compared with 45.0% of those who did not participate ($p = 0.001$; Table 3). Among those who were retained in care during the year before referral, 82.6% of those who participated in CARES were retained in care throughout the 24 months of observation as compared with 51.7% of those who did not participate ($p = 0.02$). Among those who had not been retained in care in the year before referral, 69.4% of those who participated in CARES were retained in care throughout the 24 months of observation as compared with 38.7% of those who did not participate ($p = 0.012$).

In univariate regression models, participation in CARES [odds ratio (OR) 2.94, 95% confidence interval (CI) 1.05–8.22], alcohol use (OR 2.60, 95% CI 0.93–7.27), baseline VL (OR 0.67, 95% CI 0.48–0.94), and baseline CD4 count (OR 1.56, 95% CI 1.04–2.32) were all associated with achieving viral suppression (VL \leq 200 copies/mL) at least

TABLE 1. BASELINE CHARACTERISTICS BY PARTICIPATION IN CENTER FOR ADHERENCE, RETENTION, AND ENGAGEMENT SUPPORT (CARES)

	Total (N=119), median (IQR)	Participating in CARES (n=59), median (IQR)	Referred, not participating (n=60), median (IQR)	p
Age	48 (39–53)	50 (42–54)	46.5 (37.5–51)	0.02 ^a
Baseline CD4, cells/ μ L	159 (62–301)	143 (62–256)	185.5 (57–319.5)	0.35 ^a
Baseline VL, log ₁₀ copies	4.11 (2.25–5.14)	4.17 (2.39–5.24)	3.96 (2.00–5.04)	0.36 ^a
	Total (N=119), Frequency (%)	Participating in CARES (n=59), Frequency (%)	Referred, not participating (n=60), Frequency (%)	p
Gender				1.00 ^b
Cismale	83/119 (69.8)	42/59 (71.2)	41/60 (68.3)	
Cisfemale	30/119 (25.2)	15/59 (25.4)	15/60 (25.0)	
Transgender male	1/119 (0.8)	0/59 (0)	1/60 (1.7)	
Transgender female	5/119 (4.2)	2/59 (3.4)	3/60 (5.0)	
Race				0.33 ^b
White	9/119 (7.6)	3/59 (5.1)	6/60 (10.0)	
African American	108/119 (90.8)	54/59 (91.5)	54/60 (90.0)	
Hispanic	2/119 (1.7)	2/59 (3.4)	0/60 (0)	
Homelessness				1.00 ^a
Permanent housing	42/119 (35.3)	21/59 (35.6)	21/60 (35.0)	
Homeless	77/119 (64.7)	38/59 (64.4)	39/60 (65.0)	
Education				0.49 ^b
Unknown	6/119 (5.0)	1/59 (1.7)	5/60 (8.3)	
<12th	50/119 (42.0)	24/59 (40.7)	26/60 (43.3)	
HS diploma or GED	45/119 (37.8)	25/59 (42.4)	20/60 (33.3)	
Some college	13/119 (10.9)	6/59 (10.2)	7/60 (11.7)	
College degree	5/119 (4.2)	3/59 (5.1)	2/60 (3.3)	
Substance use				
Cocaine	77/119 (64.7)	40/59 (67.8)	37/60 (61.7)	0.20 ^c
Alcohol	55/119 (46.2)	29/59 (49.2)	26/60 (43.3)	0.52 ^c
Marijuana	34/119 (28.6)	16/59 (27.1)	18/60 (30.0)	0.73 ^c
Methamphetamines	8/119 (6.7)	2/59 (3.4)	6/60 (10.0)	0.27 ^b
Mental health disorders				
Depressive and anxiety	46/119 (38.7)	31/59 (52.5)	15/60 (25.0)	0.002 ^c
Psychotic	21/119 (17.6)	13/59 (22.0)	8/60 (13.3)	0.21 ^c
Bipolar	12/119 (10.1)	4/59 (6.8)	8/60 (13.3)	0.24 ^b
PTSD	8/119 (6.7)	5/59 (8.5)	3/60 (5.0)	0.49 ^b
Baseline VL suppression	31/119 (26.1)	14/59 (23.7)	17/60 (28.3)	0.68 ^c
Baseline retention in care	52/119 (43.7)	23/59 (39.0)	29/60 (48.3)	0.36 ^c

^aWilcoxon rank-sum test.^bFisher's exact test.^cChi-square test.

CARES, Center for Adherence, Retention, and Engagement Support; IQR, interquartile range; PTSD, post-traumatic stress disorder; VL, viral load.

once during the 24 months of observation (Table 4). The association between participation in CARES and viral suppression persisted in a multi-variate model that included the aforementioned covariates [adjusted OR (AOR) 3.50, 95% CI 1.19–10.32].

Univariate regression demonstrated associations between participation in CARES (OR 3.59, 95% CI 1.65–7.79), female gender (OR 2.07, 95% CI 0.88–4.83), alcohol use (OR 2.22, 95% CI 1.05–4.72), age (OR 1.03, 95% CI 0.99–1.07), baseline CD4 count (OR 1.31, 95% CI 1.04–1.66),

TABLE 2. VIRAL SUPPRESSION BY PARTICIPATION IN CENTER FOR ADHERENCE, RETENTION, AND ENGAGEMENT SUPPORT (CARES)

	Overall	Participating in CARES	Referred, not participating	Difference [95% CI]	p
All patients	98/119 (82.4%)	53/59 (89.8%)	45/60 (75.0%)	14.8% [1.0–28.2]	0.034
VL suppressed at BL	31/31 (100.0%)	14/14 (100.0%)	17/17 (100.0%)	—	—
VL not suppressed at BL	67/88 (76.1%)	39/45 (86.7%)	28/43 (65.1%)	21.6% [3.7–38.1]	0.018

At least one VL \leq 200 copies/mL during 2-year follow-up.

BL, baseline; CARES, Center for Adherence, Retention, and Engagement Support; CI, confidence interval; VL, viral load.

TABLE 3. RETENTION IN CARE BY PARTICIPATION IN CENTER FOR ADHERENCE, RETENTION, AND ENGAGEMENT SUPPORT (CARES)

	Overall	Participating in CARES	Referred, not participating	Difference [95% CI]	p
All patients	71/119 (59.7%)	44/59 (74.6%)	27/60 (45.0%)	29.6% [12.0–44.7]	0.001
Retained in care at BL	34/52 (65.4%)	19/23 (82.6%)	15/29 (51.7%)	30.9% [4.9–51.1]	0.020
Not retained in care at BL	37/67 (55.2%)	25/36 (69.4%)	12/31 (38.7%)	30.7% [6.8–50.3]	0.012

At least two HIV medical care encounters (either two visits with a provider or one visit with a provider and one laboratory visit with viral load measurement) separated by >90 days in each year during 2-year follow-up.

BL, baseline; CARES, Center for Adherence, Retention, and Engagement Support; CI, confidence interval.

depressive/anxiety disorder (OR 1.99, 95% CI 0.91–4.34), and retention in care for the 24 months of observation (Table 5). In a multi-variate model that adjusted for these covariates, the association between participation in CARES and retention in care persisted (aOR 3.73, 95% CI 1.52–9.14).

Discussion

In this retrospective cohort study, we found that participation in CARES, a program that utilizes a multi-disciplinary team to provide individualized care for PWH through a suite of integrated services, was associated with increased retention in HIV care and viral suppression among PWH with severe substance use disorders, serious mental health conditions, and substantial psychosocial challenges, including homelessness. The majority of patients who participated in the CARES program achieved viral suppression at least once during the 24-month observation period, which was significantly higher than those who were referred but did not participate (89.8% vs. 75.0%, $p=0.034$).

CARES participants were also significantly more likely to be retained in care during the 2-year observation period (74.6% vs. 45.0%, $p=0.001$). These results were corroborated in univariate and multi-variate regression, with participation in CARES associated with higher odds of both retention in care (aOR 3.73, 95% CI 1.52–9.14) and viral suppression (aOR 3.50, 95% CI 1.19–10.32).

Unexpectedly, alcohol use was positively associated with both retention in care (OR 2.22, 95% CI 1.05–4.72) and viral suppression (OR 2.60, 95% CI 0.93–7.27). In many other settings, alcohol use has been negatively associated with retention in care, viral suppression, and other steps in the HIV care continuum.²⁷ Emerging research suggests that behavioral interventions can decrease alcohol use and improve HIV-related outcomes among PWH.²⁸ The psychosocial support available to patients at the Ponce

Center—regardless of participation in CARES—may have led to decreased alcohol use, increased engagement with the health care system, or heightened outreach efforts to patients who reported using alcohol, although the mechanism for this effect is unclear.

This association may also have been due to ascertainment bias, with patients who presented to care more frequently having additional opportunities to report alcohol use. Similarly, depressive/anxiety disorders were positively associated with retention in care (OR 1.99, 95% CI 0.91–4.34) in this analysis. Prior studies have demonstrated that mental health diagnoses are associated with lower odds of retention in care, whereas mental health service utilization has been associated with increased retention in care and improved health outcomes among PWH.¹⁶

The present findings suggest that colocalized and integrated mental health services can support engagement in care among PWH through treatment of coexisting mental health conditions, and represent an opportunity to support continued connection to HIV care. The value of integrating mental health care with HIV care has been supported by numerous recent studies,^{29–31} and is recognized as a focus area of both the domestic HIV strategy,¹⁰ and the PEPFAR strategic plan.³² In the CARES program, a key facilitator of mental health services integration was grant funding of an on-site interdisciplinary mental health provider team at the Grady Ponce Center through the federal Ryan White program, including a psychiatric nurse practitioner who was embedded as part of the core CARES clinical team.

Overall, these data demonstrate that an individualized approach to care that involves a multi-disciplinary team and integrated services can be effective for improving viral suppression and retention in care among PWH with complex psychosocial needs, and this study contributes to the still limited evidence base supporting interventions aimed at improving retention in care among this population. In previous

TABLE 4. FACTORS ASSOCIATED WITH VIRAL SUPPRESSION

	Unadjusted OR [95% CI]	p	aOR [95% CI]	p
Participating in CARES	2.94 [1.05–8.22]	0.039	3.50 [1.19–10.32]	0.023
Alcohol use	2.60 [0.93–7.27]	0.068	2.12 [0.72–6.28]	0.17
Baseline VL	0.67 [0.48–0.94]	0.020	0.79 [0.52–1.20]	0.26
Baseline CD4 ^a	1.56 [1.04–2.32]	0.03	1.34 [0.84–2.16]	0.22

At least one VL ≤ 200 copies/mL during 2-year follow-up.

^aCategorized as less than 100, 100–199, 200–299, 300–399, 400–499, and 500 cells/mL or greater.

aOR, adjusted odds ratio; CARES, Center for Adherence, Retention, and Engagement Support; CI, confidence interval; OR, odds ratio; VL, viral load.

TABLE 5. FACTORS ASSOCIATED WITH RETENTION IN CARE

	<i>Unadjusted OR [95% CI]</i>	<i>p</i>	<i>aOR [95% CI]</i>	<i>p</i>
Participating in CARES	3.59 [1.65–7.79]	0.001	3.73 [1.52–9.14]	0.004
Female gender	2.07 [0.88–4.83]	0.094	2.78 [1.06–7.32]	0.038
Alcohol use	2.22 [1.05–4.72]	0.038	2.46 [1.03–5.91]	0.044
Age	1.03 [0.99–1.07]	0.197	1.01 [0.96–1.06]	0.71
Baseline CD4 count ^a	1.31 [1.04–1.66]	0.024	1.35 [1.05–1.74]	0.018
Depressive/anxiety disorder	1.99 [0.91–4.34]	0.083	1.68 [0.68–4.13]	0.26

At least two HIV medical care encounters (either two visits with a provider or one visit with a provider and one laboratory visit with viral load measurement) separated by >90 days in each year during 2-year follow-up.

^aCategorized as less than 100, 100–199, 200–299, 300–399, 400–499, and 500 cells/mL or greater.

aOR, adjusted odds ratio; CARES, Center for Adherence, Retention, and Engagement Support; CI, confidence interval; OR, odds ratio.

studies, intensive case management and care coordination have been associated with improved engagement in care and viral suppression among PWH having substance use disorders, mental health conditions, housing insecurity, and other barriers to care.^{25,33}

At the Max Clinic in Seattle, Washington, a high intensity low-threshold incentivized care model has shown success in engaging high-need complex patients in care to achieve viral suppression.^{24,34} Walk-in access to care and relationships with clinic staff are key to supporting engagement in care in this setting.³⁵ Similarly, the POP-UP clinic in San Francisco, California, demonstrated that a low barrier high intensity incentivized care model can improve viral suppression and ART uptake among PWH with homelessness or unstable housing.²⁶

An open-access drop-in model may reduce barriers to care by allowing patients to seek care as they need it, rather than waiting on appointment availability or coordination of transportation. The lack of set appointment times can help ensure that patients are not stigmatized for being late or missing appointments. The presence of a drop-in center provides a safe, welcoming, and nonjudgmental space for patients to access HIV care, mental health programming, and social work resources, as well as food if needed.

Interventions containing these and similar elements have been successfully trialed in Seattle and other settings.^{34,36} However, the southeastern United States, a region that is burdened with more new HIV diagnoses and deaths than any other region in the country, suffers from a unique constellation of structural challenges—including low rates of insurance coverage, high rates of poverty and unemployment, limited access to public transportation, reduced availability of services, and distinct cultural factors—that complicate efforts to engage and retain PWH in care.³⁷

Atlanta is a microcosm of these factors, with high levels of food insecurity, housing insecurity, financial instability, and substance use contributing to suboptimal retention in care for the Ponce Center clinic population.¹⁴ Because of these regional disparities, the southeastern United States is a core focus of the CDC's HIV prevention efforts, and features prominently in the CDC's Ending the Epidemic Initiative.³⁷ This cross-agency initiative aims to reduce new HIV infections by 90% over the next decade by concentrating on key geographic areas, more than half of which are located in the southeast.³⁸

Innovative and intensive programming focused on HIV surveillance, prevention, and care will be critical to the suc-

cess of this initiative. The present evaluation of the CARES program supports and builds on the literature around supporting retention in care for PWH with complex needs, particularly in the southeastern region, and provides a blueprint for future programming to reduce HIV morbidity, mortality, and transmission in this setting, representing an opportunity to further the goals of the Ending the Epidemic initiative. Although this was not itself a disparities study, future research could explore whether an intervention such as the CARES model might yield outcomes that help to close gaps in HIV health outcomes, including disparities in outcomes across racial and ethnic groups.³⁹

This study also suggests possible directions for the implementation of long-acting injectable ART. This therapy holds promise for promoting adherence, especially in patients who struggle with taking daily oral medications, but requires patients to present to care regularly for medication administration.⁴⁰ Injectable cabotegravir/rilpivirine is FDA approved for patients who are virologically suppressed on a stable ART regimen.⁴¹ Although it has not yet been specifically studied in PWH with complex psychosocial needs, it may represent a valuable tool in providing care to this population. PWH coping with housing insecurity may struggle with loss of pill containers due to lack of safe storage, or miss medication doses because of food insecurity, limiting their ability to maintain adherence.⁴²

Those with substance use disorders face similar challenges, and decreased pill burden has been linked to improved adherence in this population.⁴³ PWH with mental health disorders are more likely to experience pill aversion as a barrier to adherence.⁴⁴ Delivering ART through a monthly or bimonthly injection rather than a daily (or more frequent) oral medication may result in improved adherence among PWH with complex psychosocial needs. The CARES program could represent a useful platform for implementation of long-acting injectable ART for this population.

A major strength of this analysis is that it was able to demonstrate improved outcomes among patients who participated in the CARES program as compared with those who did not participate. However, patients were not randomized, and there may have been relevant differences between those who participated in CARES and those who were referred but did not participate. Specifically, patients who chose to participate in CARES may have been more motivated to engage in care at baseline than those who were referred but did not participate, which may have biased the study to overestimate the effect of the intervention.

A randomized controlled trial is warranted for further investigation. Because the CARES program consisted of multiple components that were executed concurrently, this study was unable to assess which features of the CARES program had the greatest impact on outcomes. Qualitative analyses or dismantling studies could elucidate those aspects of the program that provided the most value for patients. Although other similar programs have featured an embedded primary care provider, this was not a component of the CARES program.³⁴

The impact of adding a dedicated primary care provider to the program's interdisciplinary team could represent an area for future research. In addition, this study took place at a single urban site where access to HIV-specific care is greater than in most clinics in other urban or rural areas and, therefore, the results may not be generalizable to other settings. Finally, a potential limitation of this care model is the cost. Significant financial support is required to sustain such a model, and it may not be sustainable in settings with limited resources. However, the costs associated with implementation of this program may be balanced by the savings from reduced transmission of HIV and decreased use of higher cost care resulting from sequelae of poorly controlled HIV. Future study could include a cost-effectiveness analysis.

Of note, consistent with the widespread disruptions in health care service delivery during the COVID-19 pandemic, implementation of infection control protocols at the Grady Ponce Center unfortunately led to the suspension of the CARES program at the height of the pandemic, although CARES patients continued to receive HIV primary care, mental health, and social services through traditional HIV care avenues during this period. Subsequent grant funding and the waning of the pandemic have allowed for the establishment of a new integrated care open access clinic initiative at the Grady Ponce Center that builds on our previous experience in implementing the CARES model, although with more staffing resources, expanded clinical space, and larger clinical capacity. This clinic comprises a dedicated transdisciplinary team of primary care and mental health providers, medical support staff, medical case managers, and patient navigators.

In summary, this analysis provides evidence that a comprehensive care model that involves an interdisciplinary team-based approach, individualized care, and integrated services can successfully increase retention in HIV care and viral suppression among PWH with complex psychosocial needs. Qualitative analysis, dismantling studies, cost assessment, and randomized controlled trials represent future directions for research.

Acknowledgments

The authors would like to thank the CARES interdisciplinary team, including Mary Etay, Reginald Avant, and Lynn van Liew; Dr. Minh Nguyen, Jeselyn Rhodes, and Cameron England for assistance with the CFAR HIV Registry and data extraction; and CFAR for financial support.

Authors' Contributions

M.G. conceptualized the study, with guidance from V.C.M. and J.A.C. M.G. applied for the CFAR grant. M.G. and S.S. performed data abstraction. S.S. and Y.C. conducted statistical analyses, with the supervision of K.E. M.G. wrote

the first draft of the article, with substantial revisions by S.S. All authors substantively edited, critically revised, and approved the final version for publication.

Author Disclosure Statement

V.C.M. has received investigator-initiated research grants (to the institution) and consultation fees (both unrelated to this study) from Eli Lilly, Bayer, Gilead Sciences, and ViiV. The other authors report no relevant financial or nonfinancial conflicts of interest.

Funding Information

This study received support from the Emory Center for AIDS Research (P30 AI050409) and Georgia Clinical and Translational Sciences Alliance (UL1TR002378).

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