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Evaluation of the Revised Versus Original Ryan White Part A HIV Care Coordination Program in a Cluster-Randomized, Stepped-Wedge Trial

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Background: To address challenges with delivery of an evidence-based HIV care coordination program (CCP), the New York City Health Department initiated a CCP redesign. We conducted a site-randomized stepped-wedge trial to evaluate effectiveness of the revised versus the original model.

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Setting: The CCP is delivered in New York City hospitals, community health centers, and community-based organizations to people experiencing or at risk for poor HIV outcomes.

Methods: The outcome, timely viral suppression (TVS), was defined as achievement of viral load <200 copies/mL within 4 months among enrollees with unsuppressed viral load ($\geq$200 copies/mL). Seventeen original-CCP provider agencies were randomized within matched pairs to early (August 2018) or delayed (May 2019) starts of revised-model implementation. Data from 3 periods were examined to compare revised versus original CCP effects on TVS. The primary analysis of the intervention effect applied fully conditional maximum likelihood estimation together with an exact, conditional *P*-value and an exact test-based 95% CI. We assigned each trial enrollee the implementation level of their site (based on a three-component measure) and tested for association with TVS, adjusting for period and study arm.

Results: Over 3 nine-month periods, 960 individuals were eligible for trial inclusion (intention to treat). The odds ratio of TVS versus no TVS comparing revised with original CCP was 0.88 (95% CI: 0.45, 1.7). Thus, the revised program yielded slightly lower TVS, although the effect was statistically nonsignificant. TVS was not significantly associated with revised-CCP implementation level.

Conclusion: Program revisions did not increase TVS, irrespective of the implementation level.

Key Words: care coordination, HIV viral suppression, surveillance, cluster-randomized stepped-wedge trial, implementation science, comparative effectiveness

INTRODUCTION

The individual-level and population-level benefits of HIV antiretroviral therapy (ART) depend on early and consistent medical care and treatment to achieve and maintain viral suppression (VS).[1–3] Care coordination and patient navigation interventions have shown some evidence of effectiveness for HIV care and treatment engagement in clinical trials and quasi-experimental evaluations.[4–15] In New York City (NYC), a comprehensive care coordination program (CCP) was launched in 2009 using federal Ryan White HIV/AIDS Program funding, which covers an array of

medical and supportive services to low-income people with HIV (PWH) in the United States.[16] CCP effectiveness findings[17,18] led the Centers for Disease Control and Prevention to designate the CCP first as an evidence-informed intervention for retention in HIV care and then as a structural evidence-based intervention for VS.[19] However, a minority of previously unsuppressed CCP clients achieved VS (43%)[20] or durable VS (21%),[21] and some CCP features were identified as implementation barriers: a rigid system of program tracks, a complex reimbursement model, and a requirement for weekly visits over a three-month "induction period."[22] Of clients enrolled, more than one-third dropped out of the program within 12 months.[17,21]

In response to the identified barriers,[22] intervention literature, and CCP evaluation findings,[20,21] the NYC Health Department and its community partner, the HIV Health and Human Services Planning Council of New York, outlined a set of CCP revisions. These revisions were integrated into the Health Department's late-2017 request for proposals initiating a competitive solicitation for CCP contracts. The request for proposals also outlined plans for an experimental evaluation using contract-level randomization to an early or delayed start of the revised model.

This article reports on the experimental component[23] of the Program Refinements to Optimize Model Impact and Scalability based on Evidence (PROMISE) study of the revised CCP. The goal of PROMISE is to investigate the impact and implementation of empirically driven course corrections to an already-effective intervention model. Drawing upon an implementation-science framework, we hypothesized that model revisions would reduce service delivery barriers and increase program fidelity and effectiveness. Specifically, we hypothesized that a higher proportion of virally unsuppressed PWH enrolling in the revised CCP would achieve timely VS (TVS), as compared with virally unsuppressed PWH enrolling in the original CCP during the same period. To test this hypothesis, we used a cross-sectional, stepped-wedge design for the rollout of the revised model in previously funded, re-awarded CCP provider agencies.[23] This study adds to the relatively scarce peer-reviewed literature on an evolving area of practice: structural care interventions addressing barriers to engagement among high-need PWH.[5,24]

MATERIALS AND METHODS

## Participants, Intervention, and Outcomes

Study Setting

Of the original 28 CCP agencies funded since 2009, 17 secured contracts under the 2017–18 resolicitation. These 17 agencies (hereafter referred to as "sites") represented all NYC counties, diverse settings (hospitals, community health centers, and community-based organizations), and a collective caseload of >2000 CCP clients. Study sites are listed at: https://clinicaltrials.gov/ct2/show/NCT03628287, and the protocol has been published.[23]

Eligibility Criteria

Sites were randomly assigned to continue original-CCP delivery or begin revised-model delivery in the initial transition (ie, step) of the stepped-wedge design (Fig. 1). PWH eligible for the trial were newly enrolled in the original or revised CCP and virally unsuppressed (HIV RNA ≥200 copies/mL) as of their latest viral load (VL) test in the year before enrollment or lacking any VL test in that year (presumed out of care[25]). The trial-eligible enrollment window for each nine-month implementation period was restricted to the first 5 months, permitting 4 months of outcome observation per enrollee before the next transition/step.

Intervention and Control Conditions

Since its inception, the CCP was designed to meet the full range of clients' medical and social service needs while building HIV self-management skills, through interdisciplinary team-based case management, patient navigation, and structured health education. The navigator was integrated into care team communications/decisions and charged with outreach and regular visits to clients in their preferred locations outside of the program setting. The original-CCP intervention has been previously described[17] and packaged in an online toolkit.[26] For this trial, the control condition was the site-level continuation of original-CCP delivery, while the intervention condition was a site-level change from original-CCP to revised-CCP delivery. The Health Department maintained study assignments by staggering sites' revised-CCP trainings and contract starts.
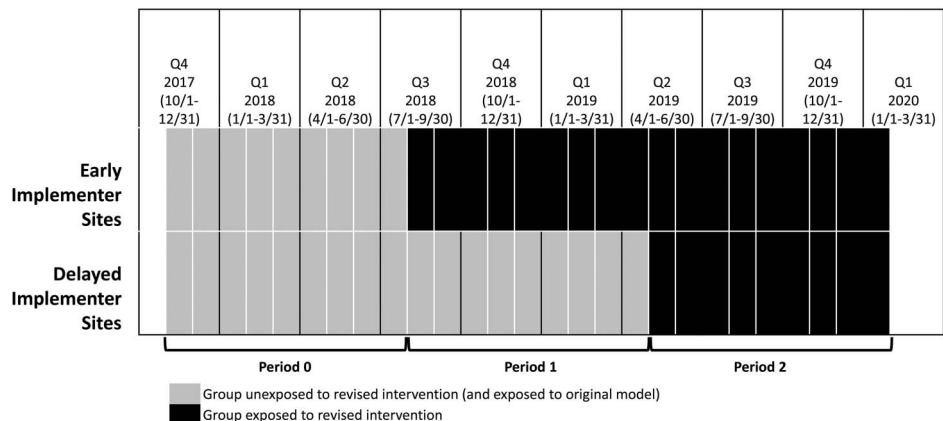
FIGURE 1. Stepped-wedge design with 3 implementation periods (2 transitions to revised intervention).

Program revisions affected service elements, modalities, and flexibility of delivery, while leaving core components of the original CCP intact.[27] Major additions included a training and toolkit for assessment and counseling around client HIV self-management[28]; videoconferencing options for certain services, such as directly observed therapy (DOT); and support for "immediate" ART (ART),[29] defined in this program as ART initiation (by PWH not on ART) within 4 days of enrollment. Changes included replacing conditional per-member-per-day reimbursement with a fee-for-service reimbursement model accounting for resource demands, such as staff travel for visits, and offering higher rates for meeting performance standards. Induction period requirements and enrollment tracks were removed in favor of flexibility. Figure 2 shows hypothesized mechanisms by which program revisions would improve TVS. Immediate ART has shown benefits for VS and time to VS.[30,31] Videoconferencing options, the elimination of enrollment tracks, and a DOT standard of at least 3 weekly observed doses were expected to broaden DOT uptake while maintaining effectiveness. Self-management assessment (SMA) was designed to inform tailored ART adherence support. The new payment structure was intended to facilitate client-centered care.

Intervention Implementation Measurement

To assess revised-CCP implementation during the trial, we identified components specific to the revised CCP: SMA (completed within 45 days of enrollment), observation of at least 3 ART doses per week for DOT clients, and adherence to updated program eligibility criteria. The first 2 components had been selected as contract-monitoring performance indicators, with 75% thresholds for success. The third component was selected as a proxy for sites' overall integration of model revisions, with a lower threshold (67%) because available surveillance and vital-statistics data captured most eligibility criteria (recent HIV diagnosis, care or treatment initiation, absences from care, unsuppressed VL, hepatitis-C coinfection, and pregnancy), but could not capture ART regimen change, missed appointments, or provider-assessed risk of care interruption or treatment failure. Using eligibility and services data for the first 5 months (enrollment window) of a given period, we classified each agency as fully implementing (meeting thresholds for all components), partially implementing (not meeting thresholds), or preimplementation (not assigned to revised-CCP delivery, ie, all sites in Period 0 and delayed-implementation sites in Period 1).

Outcome Measurement

The outcome, TVS, was defined as VL <200 copies/mL on the last VL test reported to surveillance in the 4 months after CCP enrollment (TVS = 1). Consistent with prior work,[17,20,25] those without any VL monitoring during follow-up were considered not to have achieved VS (TVS = 0). The four-month follow-up period was chosen to reflect expectations for VS achievement given universal-treatment policies and effective ART, and to align with HIV treatment guidelines supporting VL monitoring every 3–4 months for PWH on ART.[29,32,33]

Assignments

Randomization

Although the unit of analysis for the TVS outcome was the individual, the unit of randomization was the site. Characteristics and study arm assignments of the 17 sites are summarized elsewhere.[23] Sites were matched to maximize similarity on characteristics plausibly related to the outcome: site type, primary location, and program size. After
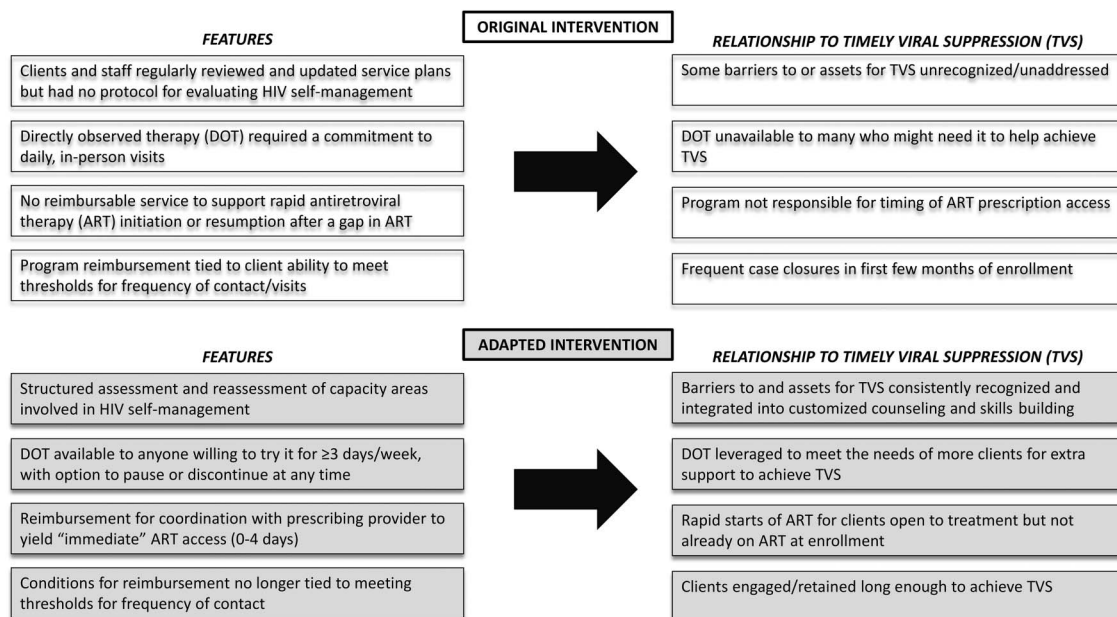

FIGURE 2. Hypothesized pathways from intervention features to outcome: TVS.

finalizing the pairs with input from team members, the lead analyst used a random-number generator in Excel to determine site assignments within pairs. Assignments were communicated as contract conditions in notifications of awards. As NYC Health Department contracts are public information, neither participants nor investigators were blinded to sites' assignments.

Data Collection, Management, and Analysis
Data Collection

The outcome measure was derived from the NYC HIV Surveillance Registry, which captures longitudinal laboratory (VL, CD4) records on all PWH in NYC HIV medical care,[34,35] regardless of specific medical provider. HIV registry data are routinely matched and merged with vital statistics and viral hepatitis surveillance data, which were leveraged to assess implementation of program eligibility criteria.

Each client's enrollment site, start date, and services were determined from the electronic System for HIV/AIDS Research and Evaluation (eSHARE), the database used for

Ryan White provider reporting to the NYC Health Department. Because the trial relied on observational data sources, there were no study-specific interactions with clients.

Data Management

All data for the trial were entered under established, required reporting, and are protected according to Centers for Disease Control and Prevention data security and confidentiality policies.[36] NYC Health Department staff conduct matches of eSHARE to surveillance data semiannually and perform continual eSHARE and surveillance data-quality checks.[37]

Statistical Analysis

We applied a fully conditional analysis that, in addition to allowing for arbitrary period effects, allows for arbitrary within-pair site differences. The analysis was based on the exact, conditional distribution theory of noncentral multiple hypergeometric distributions and their convolutions,[38] which enabled us to estimate and test the effect of the revised intervention as a single parameter. For each pair of sites, we

TABLE 1. Illustration of 2 x 3 Tables Cross-Classifying TVS and Non-TVS Outcomes by Period

		Period 0	Period 1	Period 2	Total
Site 1 in pair i (implements in Period 1)	TVS	X_{i10}	X_{i11}	X_{i12}	X_{i1+}
	No TVS	$N_{i10}-X_{i10}$	$N_{i11}-X_{i11}$	$N_{i12}-X_{i12}$	$N_{i1+}-X_{i1+}$
	Total	N_{i10}	N_{i11}	N_{i12}	N_{i1+}
Site 2 in pair i (implements in Period 2)	TVS	X_{i20}	X_{i21}	X_{i22}	X_{i2+}
	No TVS	$N_{i20}-X_{i20}$	$N_{i21}-X_{i21}$	$N_{i22}-X_{i22}$	$N_{i2+}-X_{i2+}$
	Total	N_{i20}	N_{i21}	N_{i22}	N_{i2+}
Pair i totals	TVS	X_{i+0}	X_{i+1}	X_{i+2}	X_{i++}
	No TVS	$N_{i+0}-X_{i+0}$	$N_{i+1}-X_{i+1}$	$N_{i+2}-X_{i+2}$	$N_{i++}-X_{i++}$
	Total	N_{i+0}	N_{i+1}	N_{i+2}	N_{i++}

Note: Light gray cells represent the 2 2 × 3 tables in site pair i. Dark gray cells represent the margins on which the analysis will condition, whereas white cells represent the margins calculated by summing or subtracting other fixed margins.
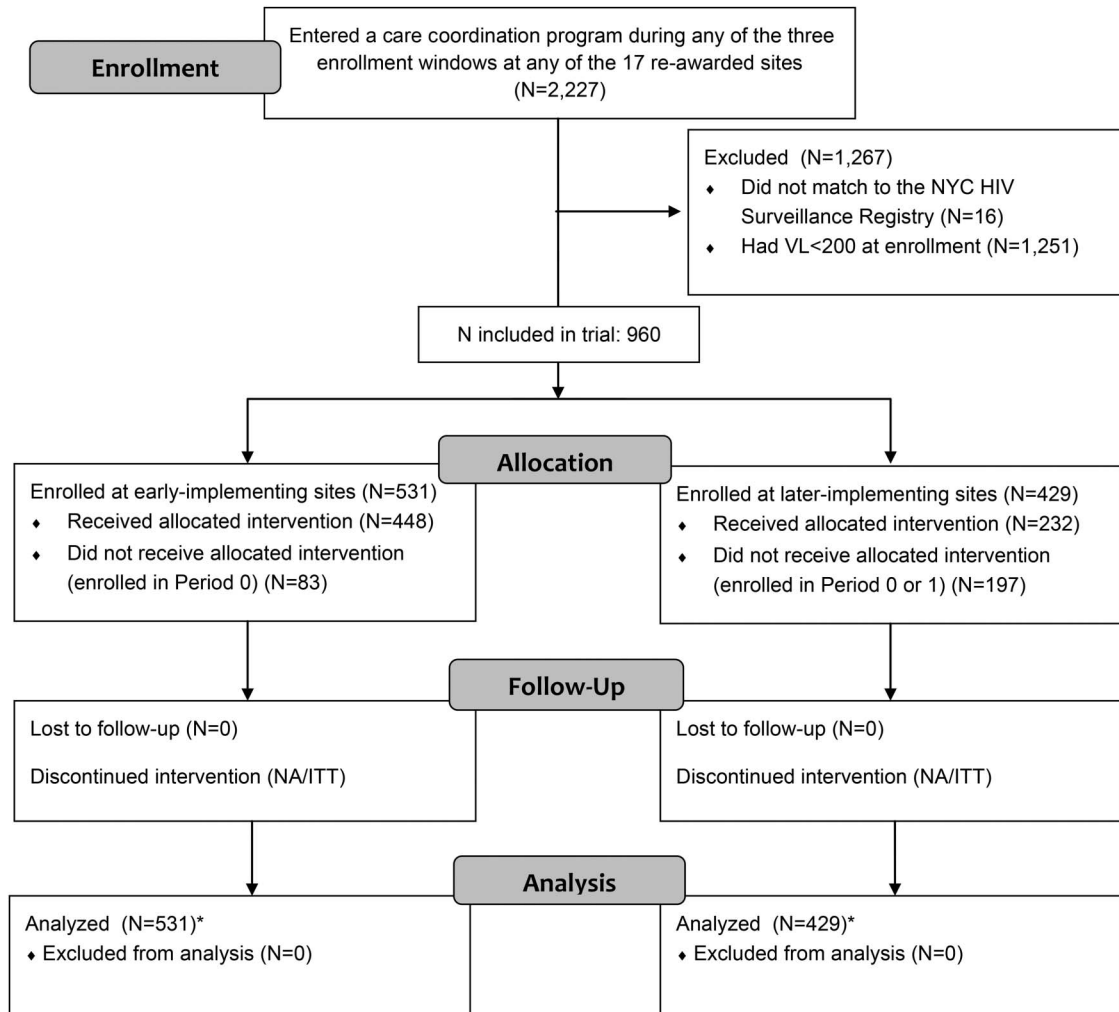
N, number; NYC, New York City; VL, viral load; NA, not applicable; ITT, intention-to-treat (design)

* The analysis utilized data from all three implementation periods (Period 0, with *no* revised program delivery; Period 1, with revised program delivery only at sites assigned to early implementation; and Period 2, with revised program delivery at all sites). Thus, all clients randomized were followed and included in the analysis.

FIGURE 3. Client-level flow diagram.

produced 2 2 × 3 tables (Table 1), cross-classifying the number of TVS and non-TVS outcomes in Period 0 (with original-CCP but no revised-CCP implementation), Period 1 (with revised-CCP implementation at sites assigned to an early start), and Period 2 (with revised-CCP implementation at all sites).

To represent the variables potentially related to TVS in the population, we used a logistic regression model containing terms for intervention and period effects plus site-pair effects and site effects within pairs, before conditioning out those nuisance parameters in the analysis. A key assumption was that any site effects would apply in each period and any period effects would apply to each site, independent of the intervention effect. Under this assumption, the constant site and period effects were allowed to vary arbitrarily from one matched pair to the next.

Once we obtained the fully conditional sampling distribution of the sufficient statistic (the number of TVS outcomes from early-switching sites in Period 1 summed over all site pairs), we calculated the conditional maximum likelihood estimate of the intervention log odds ratio with an exact, test-based 95% CI. For the primary outcome analysis, the test of the null hypothesis at the two-tailed 0.05 significance level was based on the exact two-tailed *P*-value (using the point probability definition).[38] In sensitivity analyses, we assessed the Wald, score, and likelihood ratio test results.

To test for association of TVS with implementation, we assigned each person in the trial the implementation level of their site during the period when they enrolled, and calculated ORs for TVS adjusted for period (0, 1, and 2) and study arm (early or delayed).

Sample Size

Initial power calculations, based on historical CCP data from April 2012–June 2014, found a detectable effect size (80% power with exact Type I error rate ≤0.05 two-tailed) for an OR of ~2.2, corresponding to risk ratios between 1.4 and 1.5.[23] Power calculations were updated based on the 17 re-awarded sites, postrandomization enrollment data from the 3 implementation periods, preliminary VL data for ascertaining trial eligibility (N = 933), and a base-case TVS proportion of 0.54 for the true Period 0, up from 0.44 in the original calculations. The updated simulations conditioned on actual study arm assignments, meaning early-implementing and late-implementing sites were considered fixed as randomized. The revised detectable effect size was an OR of 2.8 (risk ratio of 1.4), with power estimates ranging between ~77% and 84% for true ORs between 2.7 and 2.9.

RESULTS

Participant Recruitment/Flow

Sites

Given the NYC Health Department's control over timing of provider trainings and transitions to the revised payment structure, all 17 sites remained in their assigned study condition. However, only 3 early-implementing and 2 late-implementing sites achieved full implementation on the three-component measure, and only one early-implementing site did so in both Periods 1 and 2. Although 6 early-implementing sites (67%) met the 75% threshold for SMA in Period 1 and all 17 sites (100%) met the 75% threshold for SMA in Period 2, only 4 early-implementing sites (44%) and 5 late-implementing sites (63%) met that threshold for both SMA and DOT on transition to the revised CCP.

Individuals

Clients were not individually recruited for the trial but were enrolled in the original or revised CCP depending on the site and period in which they presented for services. Following intention-to-treat principles, all clients determined retrospectively to meet trial eligibility criteria were included in the analysis (Fig. 3). The five-month enrollment periods were November 2017 through March 2018 (Period 0, with TVS follow-up through July 2018), August through December 2018 (Period 1, with follow-up through April 2019), and May through September 2019 (Period 2, with follow-up through January 2020).

Baseline Data

A total of 960 clients met trial eligibility criteria: 176 in Period 0, 390 in Period 1, and 394 in Period 2. The 9 early-implementing sites accounted for 531 eligible clients (55.3%), while the 8 late-implementing sites accounted for 429 (44.7%). Clients at late-implementing and early-implementing sites resembled one another closely on ART status (88.8% and 90.2% on ART), baseline CD4 (43.8% and 44.1% below 200),

TABLE 2. Clients Eligible for Trial and Achieving Viral Suppression Within Four Months (TVS) by Site and Period

Pairing	Site	Study arm	Period 0 Nov. 1, 2017 - Mar. 31, 2018			Period 1 Aug. 1, 2018 - Dec. 31, 2018			Period 2 May 1, 2019 - Sep. 30, 2019		
			N unique unsuppressed clients	N suppressed within 4 months	Percent suppressed	N unique unsuppressed clients	N suppressed within 4 months	Percent suppressed	N unique unsuppressed clients	N suppressed within 4 months	Percent suppressed
1	A	Early	17	7	41.2%	44	26	59.1%	22	12	54.5%
	B	Delayed	9	5	55.6%	4	1	25.0%	19	13	68.4%
2	C	Early	17	5	29.4%	45	25	55.6%	32	18	56.3%
	D	Delayed	24	18	75.0%	16	11	68.8%	44	33	75.0%
3	E	Early	9	5	55.6%	10	7	70.0%	5	3	60.0%
	F	Delayed	10	9	90.0%	14	10	71.4%	25	17	68.0%
4	G	Early	3	1	33.3%	21	10	47.6%	2	2	100.0%
	H	Delayed	5	3	60.0%	8	2	25.0%	10	2	20.0%
5	I	Early	20	4	20.0%	56	17	30.4%	23	6	26.1%
	J	Delayed	19	10	52.6%	29	19	65.5%	68	33	48.5%
6	K	Early	1	1	100.0%	22	8	36.4%	7	3	42.9%
	L	Delayed	12	9	75.0%	18	15	83.3%	19	13	68.4%
7	M	Early	6	3	50.0%	62	34	54.8%	37	18	48.6%
	N	Delayed	6	3	50.0%	11	8	72.7%	21	5	23.8%
8	O	Early	3	2	66.7%	12	6	50.0%	9	3	33.3%
	P	Early	7	5	71.4%	14	9	64.3%	25	14	56.0%
	Q	Delayed	8	6	75.0%	4	3	75.0%	26	13	50.0%
Total (17 Sites)		ALL	176	96	54.5%	390	211	54.1%	394	208	52.8%

and VL levels (18.6% and 19.0% at 200-1499 copies/mL and 61.5% and 63.8% at 10,000 or more copies/mL) (see Table, Supplemental Digital Content 1, with baseline characteristics by arm, http://links.lww.com/QAI/B999). However, clients at late-implementing sites were more often reported to be younger than 45 years (55.3% versus 41.0%), men (68.8% versus 62.3%), White (5.8% versus 4.5%) or Asian (3.5% versus 0.0%), residents of Brooklyn (40.3% versus 27.7%) or Queens (16.6% versus 4.5%), stably housed (81.8% versus 71.2%), never incarcerated (82.8% versus 66.3%), gay or lesbian (32.9% versus 23.5%), infected through MSM transmission (40.1% versus 28.1%), uninsured (30.3% versus 10.4%), employed (31.2% versus 14.3%), living above federal poverty level (24.5% versus 14.2%), diagnosed in the 10 years before enrollment (49.6% versus 30.5%), speaking a language other than English (28.9% versus 17.7%), and born outside of the United States/US territories (44.8% versus 18.5%). They were less likely to have a report of lifetime hard-drug use (27.0% versus 33.5%) or a mental health diagnosis (34.3% versus 53.9%).

Outcomes

TVS was achieved by 96 clients (54.5%) in Period 0, 211 (54.1%) in Period 1, and 208 (52.8%) in Period 2. Table 2 summarizes site-by-period outcomes. The conditional maximum likelihood estimate of the intervention effect (log odds ratio on TVS versus no TVS comparing the revised with the original CCP) is −0.13 (95% CI: –0.80, 0.56), corresponding to an OR of 0.88 (95% CI: 0.45, 1.7). Thus, the revised program yielded slightly lower TVS rates than did the original program. However, the effect was statistically nonsignificant. There was no significant association between TVS and revised-CCP implementation; the adjusted OR for TVS was 0.92 (95% CI: 0.49, 1.72) with full implementation and 0.70 (95% CI: 0.39, 1.25) with partial implementation, relative to preimplementation (see Table, Supplemental Digital Content 2, with ORs, http://links.lww.com/QAI/B1000).

Sensitivity Analyses

See the report on primary statistical analysis, Supplemental Digital Content 3, http://links.lww.com/QAI/C2.

Sensitivity analyses using statistical tests for large-sample approximations (Wald test, score test, and generalized log-likelihood ratio) all gave similar results to the exact conditional approach used in the main analyses and did not alter the inference about revised-CCP effectiveness. In additional analyses, neither period effect differed significantly across paired sites. However, a random-effects meta-analysis showed significant heterogeneity in the pair-specific site effects (χ^2 for homogeneity = 20.8 on 7 degrees of freedom [df], $P = 0.004$). The estimated summary average of the random site effects was −0.48 corresponding to an OR on TVS (comparing early-implementing versus late-implementing sites, adjusted for period and intervention effects) of 0.62, which is not significantly different from null ($P = 0.08$).

We checked whether the overall null intervention effect could be explained by relatively small, homogeneous effects across pairs of sites or large, heterogeneous effects in opposite directions, canceling one another. Although the estimated intervention effects varied from pair to pair, the individual standard errors were large and the χ^2 homogeneity test statistic was close to its df ($\chi^2 = 9.0$ on 7 df, $P = 0.25$). We conclude that there is no significant heterogeneity in true intervention effects, and that it is reasonable to summarize the overall intervention effect as reported above.

We also conducted a partial assessment of the key analytic assumption of no period-by-site interactions within pairs of sites. Such interactions could arise through a variety of causal mechanisms and might facilitate interpretation of the overall trial findings. Although there was weak evidence of such an interaction in Period 2, its impact did not alter the overall conclusions of the primary analysis.

DISCUSSION

In a site-randomized, stepped-wedge controlled trial of the revised versus original CCP among PWH with unsuppressed VL at enrollment, there was no statistically significant intervention effect; TVS was slightly lower in the revised-CCP condition. TVS levels were essentially stable at 53%–54% during this 27-month trial (November 2017 through January 2020).

LIMITATIONS

A limitation of this trial was its focus on a single, short-term clinical outcome (TVS), which may not capture the revised or original CCP's influence on complex barriers to care and treatment engagement. Our data sources are inadequate to assess outcomes such as patient-provider communication, stress/coping, or ART adherence intention, which might more rapidly shift following program modifications. Within the 4-month follow-up period, we did observe a lower program dropout proportion (8.8% versus 14.6%) in the revised versus original CCP. However, the TVS outcome was selected due to its direct role in preserving health and preventing transmission and the early decision to build this trial around observational data sources, to avoid attrition, interference with service delivery, or unnecessary client burden. The 4-month follow-up period was determined by expectations for TVS with optimal ART access and adherence and the collective investment of program stakeholders in rapidly translating agreed-upon model revisions to real-world practice, which made any greater delay between implementation starts untenable. Statistical power was limited due to the fixed sample size, set by the original-CCP sites re-awarded contracts and the rates at which unsuppressed PWH presented for services during the 3 enrollment windows. Strengths of this trial include the site-randomized, controlled evaluation design and the fully conditional analysis, minimizing bias from self-selection, secular changes in the outcome, or site differences in factors that may influence TVS.

Generalizability

HIV epidemics and drivers of VS outcomes can vary substantially by setting, making our findings generalizable mainly to other urban areas with similar, mature HIV epidemics.

CONTEXTUALIZATION OF NULL FINDINGS

The HIV behavioral-intervention literature includes relatively few completed randomized controlled trials comparing one structured intervention with another structured intervention diverging only in certain components or mode of delivery.[7,39–42] Findings of significant outcome differences between such interventions are rare,[39,40] with some manifesting in the opposite direction from that expected.[40] A faith-based adaptation of the evidence-based "SISTA" HIV prevention intervention stands out in its demonstration of noninferiority for the primary outcome (consistent condom use) and some benefits beyond those of the original intervention,[39] perhaps due to the collaborative redesign process (with a "Church Advisory Board") and/or the testing of the intervention in the community and congregation to which it was tailored. In a Baltimore randomized controlled trial, an evidence-based case-management intervention ("Project Bridge," designed for PWH transitioning from incarceration) that was adapted to support PWH on probation/parole showed no outcome benefits over usual care.[43] The investigators suggest their null results may be tied to unrecognized commonalities between the adapted intervention and "usual care" in Baltimore.[43]

It is not clear whether our trial's findings reflect a null difference in effectiveness between the revised and original CCP (which has already shown superiority to usual care[20,21,44]) or reflect incomplete implementation of revised-CCP components during the trial. Analyses to date have not detected significant implementation variability in relation to the outcome, but our implementation measure may be insufficiently sensitive to such variability. Similarities to the original CCP and data limitations make it difficult to capture unique revised-CCP components, only one of which (SMA) is expected for every client. To avoid measuring implementation based on a single component, we included a rarely used component (DOT) and site adherence to program eligibility criteria, although this meant characterizing trial enrollees' implementation-level exposure based on broader practices at their enrollment site, not based on their individual receipt of revised-CCP components.

Although we observed no TVS benefit of the revised CCP over the original among unsuppressed enrollees, further research is needed to assess the effects of the revised CCP on the larger pool enrolled, specific subgroups, and additional (including longer-term) outcomes. Ongoing observational analyses of the revised CCP's effects (on 12-month and durable VS) relative to usual care will permit comparison with findings from similar analyses conducted for the original CCP.[20,21]

INTERPRETATION

This study's early TVS findings do not support updates to the CCP as previously packaged for replication,[26] nor do they suggest a need to roll back revisions made in NYC. Ongoing analyses will determine the extent to which the revisions facilitate reach to PWH who most need assistance or contribute to greater program engagement among PWH and providers. Much of the impetus for the program redesign came from original-CCP providers' reported implementation challenges. If the redesign reduced barriers to delivery or participation (as suggested by the lower dropout rate), without significantly reducing the CCP's short-term clinical benefits, that may be sufficient reason to continue to implement the revised intervention. Further evolution of the revised CCP is also under consideration and will be informed by additional findings from the PROMISE study.[45]

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