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Research paper

The Cooperative Re-Engagement Controlled trial (CoRECT): A randomised trial to assess a collaborative data to care model to improve HIV care continuum outcomes ☆

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ABSTRACT

Background: Persons with HIV (PWH), aware of their HIV infection but not in care account for an estimated 42.6% of HIV transmissions in the United States. Health departments and clinics implemented a collaborative data-to-care strategy to identify persons newly out-of-care with the objective of increasing re-engagement, retention in medical care, and viral load suppression

Methods: A multi-site, prospective randomised trial was conducted to identify newly out-of-care PWH using surveillance and clinic data in Connecticut (CT), Massachusetts (MA) and Philadelphia (PHL). All out-of-care participants were randomised to receive standard of care or an active public health intervention. Re-engagement in care was defined as having a documented CD4 count and/or HIV viral load within 90 days of randomization. Retention was defined as having at least two CD4 count and/or HIV viral load results $\geq$ 3 months apart within 12 months of randomization, and viral load suppression as having a viral load $<$ 200 copies/ml within 12 months of randomization.

Findings: Between August 2016 and July 2018, 1893 out-of-care participants were randomised from CT ($N = 654$), MA ($N = 630$), and PHL ($N = 609$). Participants were male (69.5%), non-Hispanic Black (48.3%) and men who have sex with men (38.8%). *Re*-engagement within 90 days was significantly higher for the intervention group overall and in all three jurisdictions (All sites: 54.9% vs 42.1%, $p < 0.0001$; CT: 51.2% vs 41.9%, $p = 0.02$; MA: 52.7% vs 44.1%, $p = 0.03$; PHL 61.2% vs 40.3%, $p < 0.0001$). Retention in care over 12 months improved overall ($p = 0.04$). Median time to viral suppression was reduced overall ($p = 0.0006$); CT ($p = 0.32$), MA ($p = 0.02$) and PHL ($p < 0.0001$).

Interpretation: This trial showed that a collaborative, data-to-care strategy, and active public health intervention led by health departments significantly increases the proportion of PWH re-engaged in HIV care and may improve retention in care and decrease time to viral suppression.

☆ The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Research in context

Evidence before this study

Data to Care (D2C) is an emerging public health strategy that uses HIV surveillance and other data to support progress along the HIV care continuum to maximize viral suppression. Despite pilot and demonstration projects using HIV surveillance data to improve HIV treatment outcomes, D2C was not a required core activity for federally funded health departments in the United States until 2018. For D2C to emerge as an evidence-based strategy, a prospective controlled trial was needed.

Added value of this study

While there have been several pilot or demonstration projects that have evaluated D2C strategies, to our knowledge, the Cooperative Re-Engagement Controlled Trial (CoRECT) is the first prospective randomised controlled trial to implement and evaluate a D2C strategy led by health departments. CoRECT, a multisite trial, was a collaborative effort between the Centers for Disease Control and Prevention (CDC) and two state (Connecticut and Massachusetts) and one local (Philadelphia) jurisdiction. The aim of the CoRECT trial was to utilize a D2C model to identify newly out-of-care people with HIV (PWH) and to test an active public health intervention to improve HIV care continuum outcomes, including linkage to and retention in care and viral suppression. Findings from this prospective, randomised controlled trial of over 1800 newly out-of-care PWH at multiple clinical sites within the three geographic regions demonstrated that overall, re-engagement in HIV care was significantly improved at all sites, while there were regional differences for retention in HIV care and viral suppression. This trial shows that re-engagement using D2C is effective, but that implementation factors at each site may contribute differently to regional outcomes for retention and viral suppression.

Implications of all the available evidence

The national goal of Ending the HIV Epidemic in the U.S. is to reduce the number of incident HIV transmissions in the U.S. by at least 90% by 2030. To achieve this goal, evidence-based strategies are needed to identify, engage, and retain PWH in care and to maximize the benefits of antiretroviral therapy. The CoRECT study found that utilizing a collaborative D2C strategy and implementing an active public health intervention improved re-engagement at all sites, including among priority populations. We found an improvement in retention in care overall; viral suppression did not improve in any jurisdiction but median time to viral suppression was reduced overall. This study provides evidence that a collaborative D2C model is an effective strategy to identify, locate, and re-engage out-of-care persons with HIV infection, including hardly reached populations. Findings from the CoRECT study suggest that a D2C strategy linked to a public health re-engagement strategy may prove beneficial to engage and re-engage the estimated 250,000 persons who are aware of their infection, but not currently receiving HIV care and treatment.

1. Background

In the United States, there is an estimated 1.2 million persons with HIV (PWH) [1]. The HIV care continuum in 2018 suggested that 86% of PWH were diagnosed, but retention in care (58%) and viral suppression (65%) remained low [2]. Achievment of viral suppression is the individual and the public health goal of treatment. Individual benefits for achieving viral suppression include improved quality of life, longer survival and not transmitting HIV sexually to others [3,4]. Public health benefits of viral suppression include a 94% reduced likelihood of transmitting HIV compared to PWH who are undiagnosed [5]. Accordingly, re-engaging newly out-of-care PWH confers important individual-level health and population-level prevention benefits, with retention in care and viral suppression as critical components of the HIV care continuum.

The national goal of Ending the HIV Epidemic in the U.S. is to reduce the number of incident HIV transmissions in the U.S. by at least 90% by 2030 [6]. To achieve this goal, evidence-based strategies are needed to identify, engage and retain PWH in care and to maximize the benefits of antiretroviral therapy.

Data to Care (D2C) is a public health strategy that uses HIV surveillance and other data (e.g. pharmacy refill data, insurance claims data) to support progress along the HIV care continuum and maximize viral suppression [7]. The primary goals of D2C are to increase the number of PWH who are engaged and retained in HIV medical care, and to increase the number who is virally suppressed. The Centers for Disease Control and Prevention (CDC) encourages health departments to utilize HIV surveillance data to identify PWH with gaps along the HIV care continuum and to intervene with them [8,9].

While there have been several pilot or demonstration projects that have evaluated D2C strategies [10–13], to our knowledge, the Cooperative Re-Engagement Controlled Trial (CoRECT) is the first prospective randomised controlled trial to implement and evaluate a D2C strategy. CoRECT, a multisite trial, was a collaborative effort between the Centers for Disease Control and Prevention (CDC) and three jurisdictions: Connecticut Department of Public Health/Yale School of Medicine, the Massachusetts Department of Public Health, and the Philadelphia Department of Public Health. The main objectives of CoRECT were to utilize a D2C model to identify newly out-of-care PWH, implement an active public health intervention and improve HIV care continuum outcomes. Here, we present findings from analyses evaluating: (1) re-engagement in HIV medical care; (2) retention in HIV medical care; and (3) viral load suppression.

2. Methods

2.1. Study design and participants

CoRECT was designed to evaluate a D2C strategy to first identify newly out-of-care persons, defined as a person who had documented previous HIV care engagement and then newly disengaged from care. PWH found to be newly out-of-care were then randomised to either an active public health intervention or the standard of care (SOC) used for re-engagement at the clinical sites throughout the study period. Standard of care varied at the 40 clinical sites involved in the trial but included communication via telephone calls, letters, or email. Outreach may have been performed by nurses, front desk staff, or case managers. Clinic staff was asked to work with disease intervention specialists (DIS) if contacted to facilitate fast track scheduling for participants. SOC may have changed over the course of the study in response to participation or for other reasons external to the study. A data-sharing partnership between health departments and HIV clinical care sites was established. Each of the three participating health departments generated a newly out-of-care list using HIV laboratory test results based on surveillance data. Collaborating HIV clinics (referred to as CoRECT clinics), recruited by each health department, generated a newly out-of-care list using appointment data. The combined out-of-care lists were reconciled by the health department and clinics, and cases were discussed at monthly conferences to

Table 1
Organizational and operational aspects of CoRECT in the three participating jurisdictions.

	Connecticut/Yale	Massachusetts	Philadelphia
Participating clinics	23 HIV specialty clinics in 4 counties	9 clinics serving PWH in 4 counties	8 clinics, one city
Clinic settings	Ryan White-funded, community-based, hospital-based and private clinics	Hospital-based, federally qualified health centres (FQHCs), public health and private practice, some with Ryan White and/or other funding to support care coordination	Ryan White funded, FQHC, academic institutions, a Veterans' Administration Medical center, private clinic
Patient identification	List of potentially newly out-of-care patients sent by health department to clinic. Clinic staff then reviewed the electronic medical record and discussed potential cases provided by the health department. Lists were compared and discussed through a reconciliation process to assess inclusion[1] and exclusion[2] criteria to generate the final eligibility list	Health department and clinics generated lists of people who appeared to be newly out-of-care by either lack of reported laboratory results or missed appointments. Lists compared for inclusion[1] and exclusion criteria[2]	Clinics submitted a monthly list all patients who had an HIV medical visit with a provider with prescribing privileges in the previous 18-months Lists compared to HIV surveillance data for inclusion[1] and exclusion[2] criteria
Reconciliation of out-of-care lists	Case conferences with clinic staff early, later central review of out-of-care lists by surveillance staff	Monthly telephone case discussions for final adjudication of a combined health department-clinic list During the initial 6 months of recruitment, some eligible candidates for randomization were held for future consideration. Randomised patients subsequently found to be ineligible were not replaced	Monthly in-person or phone case conference Eligible patients meeting inclusion and exclusion criteria were randomised Some potentially eligible patients were put on a watch list for further review
Data sharing	Secure file transfer (SFTP)	Sharing on a secure platform	Secure file transfer (SFTP)
Locating and contact methods	LexusNexis, surveillance data Phone, text, certified mail, social media, field visits	Surveillance data and Internet/social media resources. Phone, text messaging, social media, field visits	Standard procedures for location Phone, letters, home visits
Intervention components	DIS assisted with appointments, transportation, attending clinic visit, linking to services (e.g., insurance, food stamps). DIS interactions included texting, phone calls, and in-person visits. Focused primarily on re-engagement within 30 days. Once linked, there was no further engagement after 90 days. Modified ARTAS: Up to 3 sessions utilizing a strengths-based case management model. Sessions conducted over a 30-day period or until the client linked to care	Field epidemiologists assisted with appointment making and accompaniment, transportation, information and referral (e.g. HIV drug assistance program, alternate HIV care provider) Motivational interviewing. Cases were closed if initial contact was not made within 30 days. If initial contact was made, could be extended until 90 days before case closed	DIS assisted with appointments, transportation, attending clinic visit, linking to services (e.g., insurance, food stamps). A strength-based case management model, ARTAS, 90 days from date patient was located or five sessions, whichever occurred first. Timelines 90 days to locate, 90 days to link to care (or 5, and 60 days for transition after re-engagement.

Disease Intervention Specialist (DIS); Anti-Retroviral Treatment and Access to Services (ARTAS).

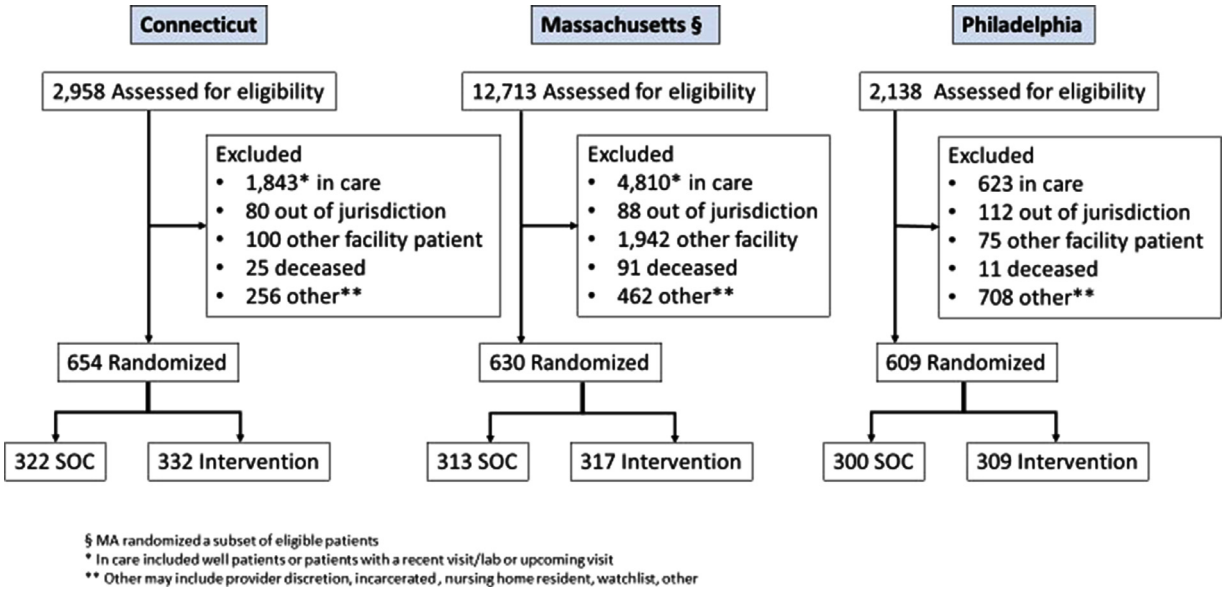


Fig. 1. Final Participant Eligibility Randomization and Disposition by Study Site.

make final determinations of those who were out-of-care. Criteria for inclusion were age ≥18 years and residence within the health department jurisdiction and meeting out-of-care criteria. A newly out-of-care person was defined as a person who had received HIV care at a collaborating CoRECT clinic within the last 12 months and then newly disengaged from care. Disengaged, was defined as not having a documented CD4 or viral load and confirmation by the participating clinic. Participants had to be out-of-care by either or both of the following definitions:

- Clinic definition: did not have a visit with a prescribing provider for more than 6 months.
- Health department definition: no objective CD4 count or viral load test result reported to health department surveillance for more than 6 months since their last measurement.

All persons determined to be newly out-of-care were then randomised to receive either usual linkage and SOC or an active public health intervention, in addition to SOC. *Local IRB ethical approval was received for each jurisdiction. Study site IRBs agreed that informed consent could not be obtained from out-of-care participants unavailable to give consent to be re-engaged in care. Informed written or verbal consent was obtained from those participants who re-engaged in care and randomised at each site.*

2.2. Study setting

Recruitment began in all three jurisdictions [Connecticut Department of Public Health/Yale School of Medicine, the Massachusetts Department of Public Health, and the Philadelphia Department of Public Health] between August-October 2016 and was completed in July 2018. Each health department created its own protocol for patient enrollment, case conferencing, and active public health intervention within the context of CoRECT specified definitions. These are summarized in Table 1.

2.3. Intervention

Participants randomised to the active public health intervention arm received field services from previously trained health department staff (DIS or field epidemiologists). The intervention differed in composition and duration at each site (Table 1). Staff activities included locating, contacting, and providing assistance in accessing HIV care; caseloads may have varied by site. Intervention services included assistance with expedited medical appointments, transportation, and access to existing community case management services. In Massachusetts (MA), field epidemiologists (who function as DIS) were used to contact, locate, assess, and re-engage patients. In Philadelphia (PHL) and Connecticut (CT), DIS used a modified evidence-based Antiretroviral Treatment and Access to Services (ARTAS) intervention [14], a patient-level, multi-session, brief, strengths-based case management intervention with demonstrated efficacy for linking newly diagnosed PWH to care, but not for re-engaging out-of-care PWH. In ARTAS, clients are encouraged to identify and use their strengths, abilities, and skills to link to medical care and accomplish other goals.

2.4. Outcomes

Objective surveillance data (CD4 count or HIV viral load reported to the health department by providers or laboratories) were used to document re-engagement, retention, and viral suppression upon which the following primary outcomes were based: re-engaged in care: CD4 count and/or HIV viral load within 90 days of randomization; 12-month retention in care: at least two CD4 count and/or HIV viral load measurements ≥ 3 months apart within 12 months of randomization; viral suppression: one HIV-1 RNA of < 200 copies/mL within 12 months of randomization.

2.5. Sample size

The target enrollment at each site was 600 out-of-care PWH (300 per arm) during a two-year enrollment period. This was based on the statistical power needed to detect an absolute increase of 10 percentage points in the proportion of patients in the intervention arm compared with standard of care who achieved a primary outcome.

2.6. Randomization and masking

Eligible participants were randomised using block randomization to either the active public health department intervention or standard of care. All randomisations were done at the individual level but stratified by clinic at all three jurisdictions. In the initial protocol, the Connecticut Department of Public Health planned to randomize patients by county but in the study stratified at the individual level within each clinic. All eligible participants at each clinic had an equal chance of being randomized to either group, intervention, or SOC. The block randomization size ranged from two (PHL, CT) to eight (MA). Bias was reduced by masking clinics from allocation decisions. The clinics did not receive any details about the randomization allocation. Clinics did, however, know which participants were enrolled in the study and may have used their own methods for re-engaging out-of-care patients. Allocation occurred within 10 days of the monthly case conference reconciliation process. Intervention staff received only the list of names of those participants randomised to the intervention arm, while clinics were blinded to any allocation status. Each site determined its own participant recruitment procedures following a structured flow of enrollment and randomization methods (Fig. 1). In Connecticut, randomization was done by Yale School of Medicine research staff through the REDCap data management system. In Massachusetts and Philadelphia randomization was performed in SAS 9.3 by health department staff.

2.7. Statistical analysis

The primary outcomes were compared by study arm overall and for each site. We calculated the proportion of patients who achieved re-engagement, retention in care and viral suppression. We then compared by study arm demographic and clinical variables. Demographic variables included: sex at birth, current gender, race/ethnicity, age (median, IQR) at time of randomization, and HIV transmission category designated at the time of diagnosis (heterosexual, male sex with male (MSM), injection drug use (IDU), MSM and IDU, or other (no identified risk, perinatal). Clinical variables included: date of HIV diagnosis (median, IQR), a categorical variable for the last viral load (VL) prior to randomization (<200, 200–1000, 1001–10,000, > 10,000 copies/mL, and a categorical variable of the last CD4 count prior to randomization (<50, 51–199, 200–350, 351–499, ≥ 500 copies/μL). Demographic and clinical characteristics were compared between study arms with a chi-square test or Fisher's exact test for proportions. Rank sum test was used for continuous variables. The overall analysis was a pooled analysis. Statistical significance was defined as $p < 0.05$. For a time-to-event analysis, a Kaplan-Meier curve and a log-rank test were used to compare time to achieving re-engagement in care in the two study arms. A subject was considered censored when he or she did not meet the study definition of re-engaging (documented CD4 or VL within 90 days of randomization). For these time-to-event analyses, time was defined as days since randomization. All statistical analyses were conducted using SAS® version 9.4 This trial is registered with ClinicalTrials.gov, number NCT02693145.

Table 2
CoRECT demographic and clinical care characteristics at Baseline.

Demographics	Intervention N(%)	Standard of Care N(%)	Total/Overall N(%)
Total			
All Sites	958 (50.6%)	935 (49.4%)	1893
Connecticut	332 (50.8%)	322 (49.2%)	654
Massachusetts	317 (50.3%)	313 (49.7%)	630
Philadelphia	309 (50.7%)	300 (49.3%)	609
Male (birth sex)			
All Sites	672 (70.1%)	644 (68.9%)	1316 (69.5%)
Connecticut	211 (63.5%)	197 (61.2%)	408 (62.4%)
Massachusetts	226 (71.3%)	232 (74.1%)	458 (72.7%)
Philadelphia	235 (76.1%)	215 (71.7%)	450 (73.9%)
Current Gender			
All Sites			
Transgender	14 (1.5%)	15 (1.6%)	29 (1.5%)
Connecticut			
Transgender	1 (0.30%)	2 (0.62%)	3 (0.46%)
Massachusetts			
Transgender	2 (0.63%)	4 (1.28%)	6 (0.95%)
Philadelphia			
Transgender	11 (3.6%)	9 (3.0%)	20 (3.3%)
Race/Ethnicity			
All Sites			
Black	460 (48.0%)	455 (48.7%)	915 (48.3%)
White	237 (24.7%)	245 (26.2%)	482 (25.5%)
Hispanic	239 (25.0%)	213 (22.8%)	452 (23.9%)
Other	22 (2.3%)	22 (2.3%)	44 (2.3%)
Connecticut			
Black	123 (37.1%)	141 (43.8%)	264 (40.4%)
White	63 (19.0%)	72 (22.4%)	135 (20.6%)
Hispanic	138 (41.6%)	104 (32.3%)	242 (37.0%)
Other	8 (2.4%)	5 (1.6%)	13 (2.0%)
Massachusetts			
Black	134 (42.3%)	119 (38.0%)	253 (40.2%)
White	113 (35.6%)	118 (37.7%)	231 (36.7%)
Hispanic	65 (20.5%)	69 (22.0%)	134 (21.3%)
Other	5 (1.6%)	7 (2.2%)	12 (1.9%)
Philadelphia			
Black	203 (65.7%)	195 (65.0%)	398 (65.3%)
White	61 (19.7%)	55 (18.3%)	116 (19.0%)
Hispanic	36 (11.6%)	40 (13.3%)	76 (12.5%)
Other	9 (2.9%)	10 (3.3%)	19 (3.1%)
Age Median years (IQR)			
All Sites	46.0 years (34–54)	45.5 years (34–53)	46.0 years (34–54)
Connecticut	47.5 years (36–56)	46.0 years (34–55)	47.0 years (32–52)
Massachusetts	47.0 years (35–55)	46.0 years (36–54)	47.0 years (36–54)
Philadelphia	41.0 years (32–52)	41.5 years (32–52)	41.0 years (32–52)
Transmission Category[†]			
All Sites			
MSM, MSM/HET	376 (39.2%)	359 (38.4%)	735 (38.8%)
IDU (IDU or HET/IDU)	198 (20.7%)	174 (18.6%)	372 (19.6%)
MSM/IDU or MSM/HET/IDU	37 (3.9%)	54 (5.8%)	91 (4.8%)
HET	213 (22.2%)	223 (23.8%)	436 (23.0%)
Other (Peri/NIR/Other)	134 (14.0%)	125 (13.4%)	259 (13.7%)
Connecticut			
MSM, MSM/HET	94 (28.3%)	100 (31.1%)	194 (29.7%)
IDU (IDU or HET/IDU)	95 (28.6%)	83 (25.8%)	178 (27.2%)
MSM/IDU or MSM/HET/IDU	8 (2.4%)	14 (4.3%)	22 (3.4%)
HET	97 (29.2%)	93 (28.9%)	190 (29.1%)
Other (Peri/NIR/Other)	38 (11.4%)	32 (9.9%)	70 (10.7%)
Massachusetts			
MSM, MSM/HET	133 (42.0%)	129 (41.2%)	262 (41.6%)
IDU (IDU or HET/IDU)	34 (10.7%)	40 (12.8%)	74 (11.7%)
MSM/IDU or MSM/HET/IDU	14 (4.4%)	18 (5.7%)	32 (5.1%)
HET	47 (14.8%)	43 (13.7%)	90 (14.3%)
Other (Peri/NIR/Other)	89 (28.1%)	83 (26.5%)	172 (27.3%)
Philadelphia			
MSM, MSM/HET	149 (48.2%)	130 (43.3%)	279 (45.8%)
IDU (IDU or HET/IDU)	69 (22.3%)	51 (17.0%)	120 (19.7%)
MSM/IDU or MSM/HET/IDU	15 (4.8%)	22 (7.3%)	37 (6.1%)

(*continued on next page*)

Table 2 (*continued*)

Demographics	Intervention N(%)	Standard of Care N(%)	Total/Overall N(%)
HET	69 (22.3%)	87 (29.0%)	156 (25.6%)
Other (Peri/NIR/Other)	7 (2.3%)	10 (3.3%)	17 (2.8%)
Clinical Characteristics			
HIV Diagnosis Median years (IQR)			
All Sites	11 years (6–19)	12 years (6–18)	12 years (6–18)
Connecticut	15.0 years (7–21)	13.0 years (6–19)	14.0 years (6–20)
Massachusetts	11.0 years (6–19)	12.0 years (5–18)	11.5 years (6–18)
Philadelphia	9 years (5–16)	11.0 years (6–15)	10.0 years (6–16)
Last Viral Load in Year Prior to Randomization			
All Sites			
< 200 copies/mL.	536 (75.1%)	519 (73.9%)	1055 (74.5%)
200–1000 copies/mL.	29 (4.1%)	34 (4.8%)	63 (4.4%)
1001–10,000 copies/mL.	53 (7.4%)	52 (7.4%)	105 (7.4%)
>10,000 copies/mL.	96 (13.4%)	97 (13.8%)	193 (13.6%)
Connecticut			
< 200 copies/mL.	159 (73.6%)	161 (74.9%)	320 (74.2%)
200–1000 copies/mL.	12 (5.6%)	13 (6.1%)	25 (5.8%)
1001–10,000 copies/mL.	16 (7.4%)	19 (8.8%)	35 (8.1%)
> 10,000 copies/mL.	29 (13.4%)	22 (10.2%)	51 (11.8%)
Massachusetts			
< 200 copies/mL.	186 (78.15%)	199 (79.6%)	385 (78.9%)
200–1000 copies/mL.	6 (2.52%)	10 (4%)	16 (3.3%)
1001–10,000 copies/mL.	13 (5.46%)	10 (4%)	23 (4.7%)
> 10,000 copies/mL.	33 (13.87%)	31 (12.4%)	64 (13.1%)
Philadelphia			
< 200 copies/mL.	191 (73.5%)	159 (67.09%)	350 (70.4%)
200–1000 copies/mL.	11 (4.2%)	11 (4.64%)	22 (4.4%)
1001–10,000 copies/mL.	24 (9.2%)	23 (9.7%)	47 (9.5%)
> 10,000 copies/mL.	34 (13.1%)	44 (18.57%)	78 (15.7%)
Last CD4 in Year Prior to Randomization			
All Sites			
≤50 cells/μL	12 (1.8%)	11 (1.6%)	23 (1.7%)
51–199 cells/μL	62 (9.2%)	72 (10.8%)	134 (10.0%)
200–350 cells/μL	100 (14.9%)	98 (14.6%)	198 (14.8%)
351–499 cells/μL	143 (21.3%)	142 (21.2%)	285 (21.2%)
≥ 500 cells/μL	353 (52.7%)	348 (51.9%)	701 (52.3%)
Connecticut			
≤50 cells/μL	2 (1.1%)	5 (2.7%)	7 (1.9%)
51–199 cells/μL	24 (13.2%)	29 (15.3%)	53 (14.3%)
200–350 cells/μL	33 (18.1%)	21 (11.1%)	54 (14.6%)
351–499 cells/μL	39 (21.4%)	36 (19.0%)	75 (20.2%)
≥ 500 cells/μL	84 (46.1%)	98 (51.8%)	182 (49.1%)
Massachusetts			
≤50 cells/μL	6 (2.5%)	4 (1.6%)	10 (2.0%)
51–199 cells/μL	16 (6.7%)	21 (8.4%)	37 (7.6%)
200–350 cells/μL	30 (12.5%)	39 (15.7%)	69 (14.1%)
351–499 cells/μL	52 (21.8%)	49 (19.7%)	101 (20.7%)
≥ 500 cells/μL	135 (56.5%)	136 (54.6%)	271 (55.5%)
Philadelphia			
≤50 cells/μL	4 (1.6%)	2 (0.9%)	6 (1.2%)
51–199 cells/μL	22 (8.8%)	22 (9.4%)	44 (9.1%)
200–350 cells/μL	37 (14.9%)	38 (16.3%)	75 (15.6%)
351–499 cells/μL	52 (20.9%)	57 (24.5%)	109 (22.6%)
≥ 500 cells/μL	134 (53.8%)	114 (48.9%)	248 (51.5%)

† MSM = Men who have sex with men; IDU- Injection drug use; HET = Heterosexual; Peri = Perinatal; NIR = Not in record.

3. Results

3.1. Baseline characteristics

The number of newly out-of-care PWH randomised by site was: CT: 654 (332 intervention and 322 SOC); MA: 630 (317 intervention and 313 SOC); PHL: 609 (309 intervention and 300 SOC) for a total of 1893 (958 intervention and 935 SOC). Demographic variables did not differ by study arm at any of the three sites, although there were differences in study populations between jurisdictions (Table 2). Most participants were male: CT 62.4%, MA 72.7%, PHL 73.9%. The largest race/ethnicity group was non-Hispanic Black: CT 40.4%, MA, 40.2%, PHL 65.3%. Of those participants with data available, last VL prior to randomization was < 200 copies/mL in a large proportion: CT 74.2%, MA 78.9%, PHL 70.4%.

3.2. Re-engagement in HIV care

Comparing the intervention to SOC, re-engagement outcomes were: All sites 525 (54.9%) vs 394 (42.1%) ($p < 0.0001$); CT 170 (51.2%) vs 135 (41.9%) ($p = 0.02$); MA, 167 (52.7%) vs 138 (44.1%) ($p = 0.03$); PHL, 189 (61.2%) vs 121 (40.3%) ($p < 0.0001$) (Fig. 2).

The intervention improved re-engagement at 90 days across various high priority subgroups and analysis of demographic and clinical characteristics by study arm for all participants who re-engaged in care is reported in Table 3. In all three sites, the time to re-engaging in care was faster in the intervention group compared to SOC; All sites (Log-Rank p= < 0.0001); CT (Log-Rank p = 0.005); MA (Log-Rank p = 0.001); PHL (Log-Rank p = < 0.0001) (Fig. 3).

3.3. Retention in HIV care

The intervention significantly improved retention in HIV care within 12 months of randomization overall due to results in PHL. Retention did not improve in CT or MA (Fig. 2). Retention outcomes for intervention vs SOC were as follows: All sites, 490 (51.2%) vs 435 (46.5%) (p = 0.04); CT, 176 (53.0%) vs 167 (51.9%) (p = 0.77); MA, 139 (43.9%) vs 144 (39.9%) (p = 0.59); PHL, 177 (56.6%) vs 129 (41.3%) (p = 0.0002).

3.4. Viral suppression

Comparing intervention to SOC for achieving viral suppression within 12 months of randomization, the results were as follows: All sites, 615 (64.2%) vs 575 (61.5%) (p = 0.22); CT, 225 (67.8%) vs 198 (61.5%) (p = 0.09); MA, 197 (62.1%) vs 204 (65.2%) (p = 0.43); PHL, 193 (62.5%) vs 173 (57.7%) (p = 0.23) (Fig. 2). Among all participants with viral suppression during the 12-month follow-up, median time to viral suppression after randomization comparing intervention vs SOC were: All sites: 76 days (IQR = 33–164, n = 615) vs 100 days (IQR = 49–194, n-575); p = 0.0006; CT: 85 days (IQR = 40.0–196.0, n = 225) vs. 104 days (IQR = 54.0–176.0, n = 198); p = 0.32; MA: 76 days (IQR = 36.0–155.0, n = 197) vs. 95 days (IQR = 43.0–209.0, n = 204); p = 0.02; PHL: 64 days (IQR = 20.0–138.0, n = 193) vs. 102 days (IQR = 50.0–198.0, n = 173); p < 0.0001 [Supplementary Fig. 1].

4. Discussion

This trial is the first multi-site randomised controlled trial to evaluate D2C linked with an active public health intervention strategy on care re-engagement, 12-month retention in care, and viral suppression among PWH newly out-of-care. Importantly, those receiving the public health intervention were significantly more likely to re-engage in HIV care within 90 days relative to standard of care and these findings remained robust for each of the three study sites. Moreover, the time to re-engagement in HIV care was faster overall and at each participating site. For distal outcomes, 12-month retention in care and viral suppression findings varied by jurisdiction.

These findings fill an important gap in intervening along the HIV care continuum. Using HIV surveillance data to improve engagement in HIV care and prevent new HIV infections began almost a decade ago [10,15,16]. These early studies found that HIV surveillance could be useful for monitoring HIV care patterns [10], and facilitating engagement, re-engagement and retention in care [16]. In 2018, D2C became a required core strategy and activity for federally-funded health departments to implement as part of an

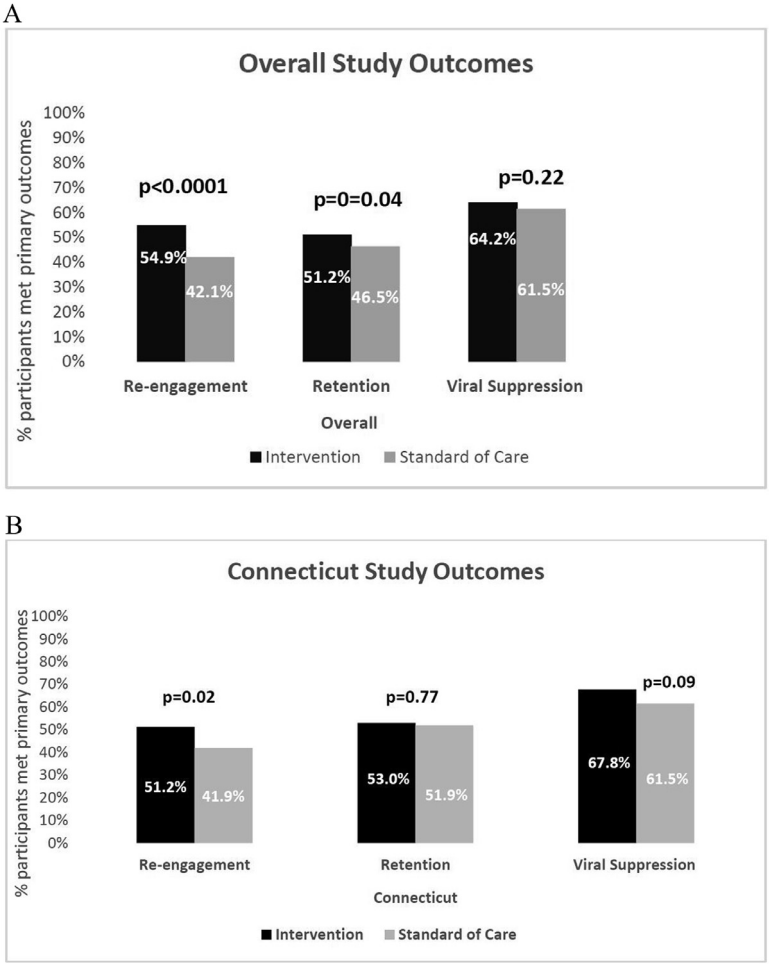


Fig. 2. HIV Treatment Outcomes (Re-engagement, Retention, and Viral Suppression) for Out-of-care PWH; Overall and in Three Jurisdictions by Study Arm.

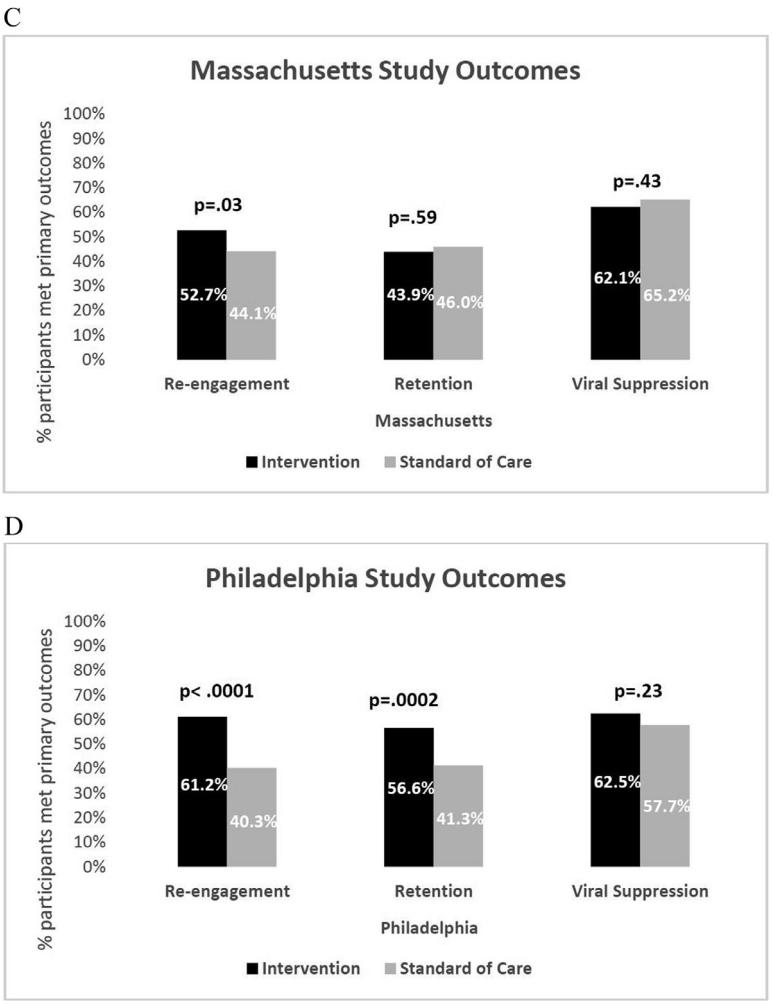


Fig. 2. Continued

integrated HIV surveillance and prevention program [8]. CoRECT employed a collaborative D2C model whereby the health department and clinical providers held joint case conferences to review and determine the final care status for all persons generated using surveillance data. This coordinated effort utilized surveillance to identify those newly out-of-care, which was refined by contributions from clinical care providers to refine the determination of who was out-of-care. We believe that this collaborative model was an essential element to accurately identify and target patients who had truly disengaged from care. These findings build on a proof of concept study in Maryland utilizing expanded D2C similarly found that combining surveillance with clinic data generated a more accurate depiction of care engagement and increased the efficiency of D2C [17].

In addition to the collaborative D2C model, a critical element for CoRECT was the implementation of an active public health intervention using DIS or field epidemiologists to locate, contact, and provide assistance with re-engagement in care. Traditionally, in health departments, DIS are assigned to sexually transmitted disease prevention and use their investigative skills to assist with HIV partner notification and other infectious disease control efforts, such as viral hepatitis and tuberculosis outbreak response [18]. More recently they have been used as patient navigators in expanded relationships with health care providers to ensure that patients are linked to care. Relative to clinic-based case managers, DIS have the unique advantage of not requiring patients to sign a release of medical information to engage them. One project utilizing DIS as expanded partner services advocates found that D2C could be incorporated into partner services, but the DIS spent considerable time working on initial assignments contacting potential out-of-care clients when fewer than a quarter of the clients were truly out-of-care [19]. In CoRECT, the routine duties of DIS and field epidemiologist varied by study site. Some were exclusively working on locating out-of-care PWH while others added this to their traditional roles and responsibilities predominantly related to sexually transmitted infections. Given the robust improvement in re-engagement, jurisdictions should consider adjusting workload or workflow models to incorporate and prioritize re-engagement into public health field services of persons out of HIV care.

Overall, the intervention improved re-engagement at 90 days across various high priority subgroups including non-Hispanic Black persons, MSM, and people who inject drugs (PWID). These improvements are notable because non-Hispanic Black persons make up the largest proportion of PWH, MSM are the population most affected by HIV in the U.S. and drug injection has created prevention and clinical management challenges and placed new populations at risk for HIV [20,21]. In particular, the epidemic of opioid use disorder has been associated with several HIV outbreaks, increasing the number of marginalized, young PWID living with HIV infection who are at higher risk for disruption of medical care engagement [22–24].

Table 3
Analysis of demographic and clinical characteristics to assess who re-engaged in care by study arm. §.

Characteristics	Intervention	Standard of Care	p value
Race/Ethnicity			
All Sites			
Black	124/239 (51.9%)	82/213 (38.5%)	0.004
White	139/237 (58.6%)	108/245 (44.1)	0.001
Hispanic	255/460 (55.4%)	200/455 (44.0%)	0.0005
Other	8/22 (36.4%)	4/22 (18.2%)	0.31*
Connecticut			
Black	55/123 (44.7%)	63/141 (44.7%)	1.00
White	44/63 (69.8%)	27/72 (37.5%)	0.0002
Hispanic	69/138 (50.0%)	44/104 (42.3%)	0.24
Other	2/8 (25.0%)	1/5 (20.0%)	1.00*
Massachusetts			
Black	68/134 (50.7%)	60/119 (50.4%)	0.96
White	62/113 (54.9%)	51/118 (43.2%)	0.08
Hispanic	35/65 (53.9%)	26/69 (37.7%)	0.06
Other	2/5 (40.0%)	1/7 (14.3%)	0.52*
Philadelphia			
Black	132/203 (65.0%)	77/195 (39.5%)	< 0.0001
White	33/61 (54.1%)	30/55 (54.6%)	0.96
Hispanic	20/36 (55.6%)	12/40 (30.0%)	0.02
Other	4/9 (44.4%)	2/10 (20.0%)	0.35*
Age Median years (IQR)			
All Sites	46.0 (34.0–54.0)	45.0 (34.0–53.0)	0.54**
Connecticut	47.5 (36.0–56.0)	46.0 (34.0–55.0)	0.68**
Massachusetts	47.0 (35.0–55.0)	46.0 (35.0–54.0)	0.70**
Philadelphia	41.0 (32.0–52.0)	41.5 (32.0–52.0)	0.81**
Transmission Category†			
All Sites			
MSM, MSM/HET	193/376 (51.3%)	137/359 (38.2%)	0.0003
IDU (IDU or HET/IDU)	120/198 (60.6%)	80/174 (46.9%)	0.005
MSM/IDU or MSM/HET/IDU	19/37 (51.4%)	20/54 (37.0%)	0.18
HET	117/213 (54.9%)	91/223 (40.8%)	0.003
Other (Peri/NIR/Other)	77/134 (57.5%)	66/125 (52.8%)	0.45
Connecticut			
MSM, MSM/HET	45/94 (47.9%)	34/100 (34.0%)	0.05
IDU (IDU or HET/IDU)	52/95 (54.7%)	42/83 (50.6%)	0.58
MSM/IDU or MSM/HET/IDU	5/8 (62.5%)	5/14 (35.7%)	0.34*
HET	43/97 (44.3%)	38/93 (40.9%)	0.63
Other (Peri/NIR/Other)	25/38 (65.8%)	16/32 (50.0%)	0.18
Massachusetts			
MSM, MSM/HET	68/133 (51.1%)	53/129 (41.1%)	0.10
IDU (IDU or HET/IDU)	21/34 (61.8%)	14/40 (35.0%)	0.02
MSM/IDU or MSM/HET/IDU	6/14 (42.9%)	8/18 (44.4%)	0.93
HET	25/47 (53.2%)	19/43 (44.2%)	0.39
Other (Peri/NIR/Other)	47/89 (52.8%)	44/83 (53.0%)	0.98
Philadelphia			
MSM, MSM/HET	80/149 (53.7%)	50/130 (38.5%)	0.01
IDU (IDU or HET/IDU)	47/69 (68.1%)	24/51 (47.1%)	0.02
MSM/IDU or MSM/HET/IDU	8/15 (53.3%)	7/22 (31.8%)	0.19
HET	49/69 (71.0%)	34/87 (39.1%)	0.0001
Other (Peri/NIR/Other)	5/7 (71.4%)	6/10 (60.0%)	0.63
Not Virally Suppressed in year prior to randomization			
All Sites	96/180 (53.3%)	74/184 (40.2%)	0.01
Connecticut	21/57 (36.8%)	25/54 (46.3%)	0.31
Massachusetts	31/54 (63.0%)	22/52 (42.3%)	0.12
Philadelphia	44/69 (63.8%)	27/78 (34.6%)	0.0004
CD4 count < 200 cells/μL in year prior to randomization			
All Sites	37/76 (48.7%)	38/84 (45.2%)	0.66
Connecticut	9/26 (34.6%)	15/34 (44.1%)	0.46
Massachusetts	12/23 (52.2%)	13/26 (50.0%)	0.88
Philadelphia	16/27 (59.3%)	10/24 (41.7%)	0.21

§ This table only includes patients that achieved the re-engagement outcome.
† MSM = Men who have sex with men; IDU- Injection drug use; HET = Heterosexual; Peri = Perinatal; NIR = Not in record.
*Fisher's Exact Test used because of small sample size.
**Rank Sum Test used for continuous variables.

As part of the collaborative data reconciliation process between health departments and clinics, many clinics reached out to those who were identified to re-engage them through SOC, not knowing of patient allocation to intervention. Nonetheless, the intervention benefit over SOC remained. While we do not know which components of the active public health intervention promoted re-engagement, both the DIS and field epidemiologist used several techniques which may have facilitated re-engagement. Motivational interviewing or a strengths-based case management model may have helped out-of-care participants increase self-efficacy and better navigate the healthcare system. The importance of a "warm handoff" in which health workers (using telephone calls, text messages, and escorting patients to medical visits) ensure that PWH are linked to a clinic for treatment in a timely manner is some-

thing that has been successfully demonstrated by the global test and treat trials [25–27]. Similarly, in CoRECT we speculate that the "warm handoff" provided by the active public health intervention resulted in improved and expedited re-engagement at all study sites. In contrast, the SOC for re-engagement generally consisted of traditional healthcare institutional methods of appointment reminders, messages, and phone calls, without the personal involvement that was an important part of the intervention.

Although the CoRECT trial demonstrated the effectiveness of the intervention to improve re-engagement, that did not extend to retention in care in two of the three jurisdictions and viral suppression in any of the three. One hypothesis is that the intervention focused primarily on re-engagement and did not continue to work with patients beyond re-engagement, which without sustained intervention, resulted in them becoming disengaged from care potentially for the very reasons they did initially. This is supported by a retrospective cohort study that examined whether persons reengaged in HIV care by public health workers remained engaged in care over a 1 to 5-year period; 34% were subsequently out-of-care in the follow-up years and most in their first (40%) and second (30%) follow-up years [28]. This highlights the need for two potential supplemental strategies: 1) the need to address underlying and persistent population-, system-, facility- and individual-level barriers to care such as addressing stigma, social determinants of health, essential support services and racial/ethnic health inequities; 2) and identifying effective interventions and services to promote retention which could either result in the DIS maintaining a chronic case load of individuals at high risk for disengage-

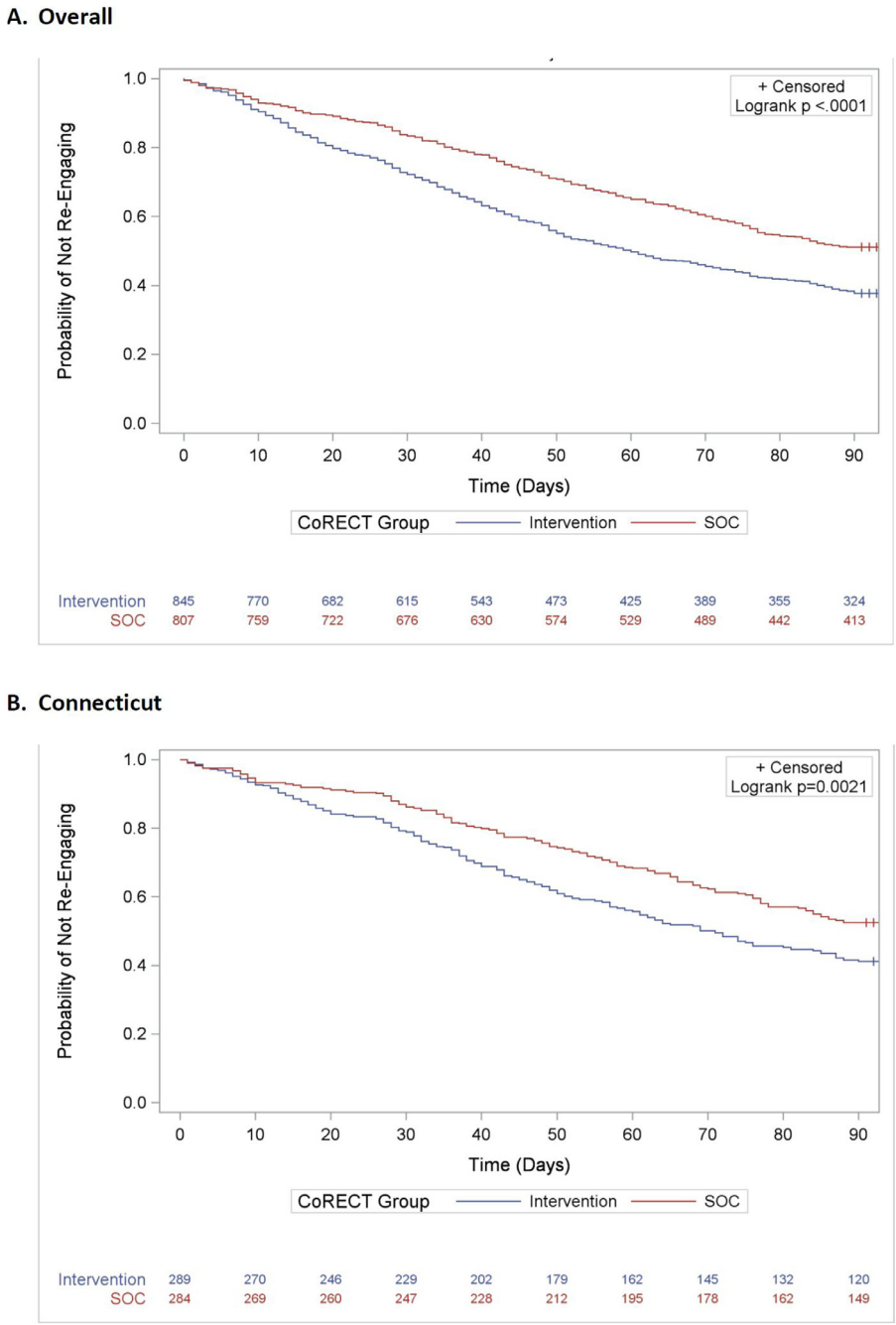
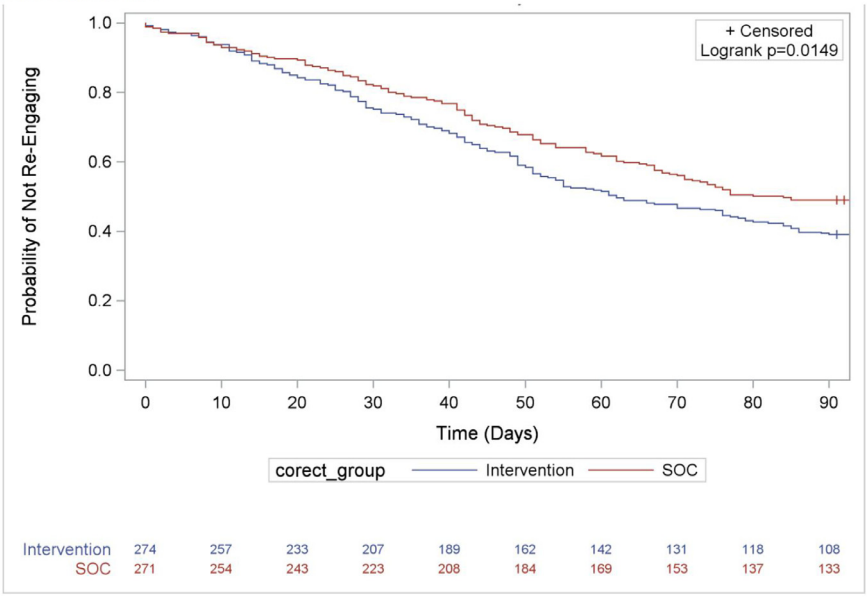


Fig. 3. Time to Re-engagement in Care (defined objectively as CD4 or VL within 90 days of Randomization) for Outof-care PWH Overall and in Three Jurisdictions by Study Arm. A=Overall; B=Connecticut; C= Massachusetts; D=Philadelphia.

C. Massachusetts



D. Philadelphia

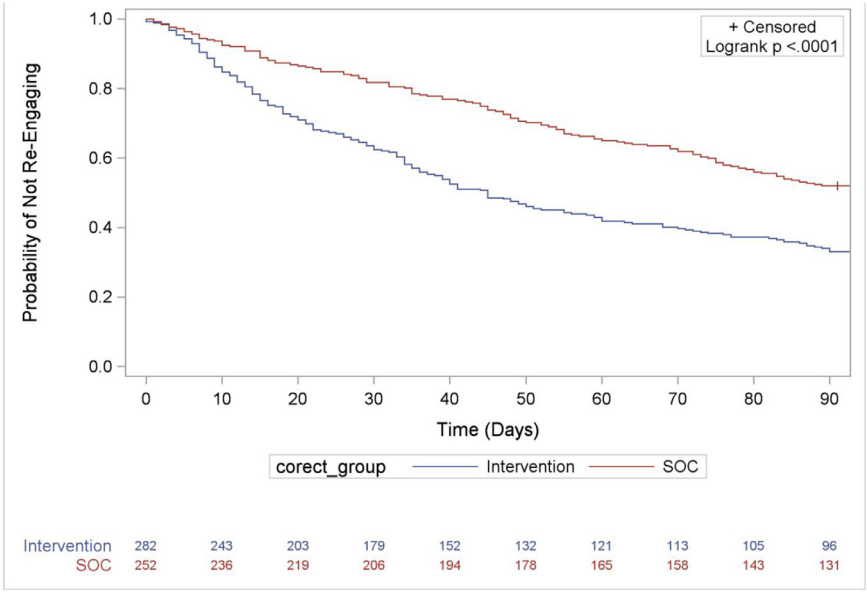


Fig. 3. Continued

ment (which may require additional training, resources and supervisory support for this additional role) or more effective linkages to case managers or other patient navigators who are skilled with working with more challenging patients. Such interventions may require novel approaches that do not rely solely on face-to-face visits in the clinics but rely more on addressing underlying social determinants of health which impact access to care. Alternatively, effectively linking clinics to clinic-based case management might have ensured that not only were they linked, but better engaged in care. Unlike the DIS, case managers must have signed release of information to engage in clinic retention. Additional interventions to promote retention are therefore needed once persons successfully re-engage in care.

It is noteworthy that in Philadelphia, retention in care at 12 months was sustained which contributed to retention improving overall; additional analyses are needed to better understand which features or components of the intervention may have contributed to this outcome; in Philadelphia case-conferences were held monthly and in person (other sites conduced case-conferences monthly and by telephone), the intervention included a longer locating eligibility period (up to 90 days vs 30 days at other sites), a transition to care element was included (up to 60 days after re-engagement at the CoRECT clinic) and minimal modifications were made to the ARTAS model, which encourages the client to identify and use personal strengths to create an action plan for being linked to medical care. Additional analyses are needed to better

understand which features or components of the intervention may have played a role

The Ending the HIV Epidemic in the U.S. initiative aims to end the HIV epidemic in the United States by 2030 and is built on four "pillars" (Diagnose, Treat, Prevent, Respond) [6]. Two of the three CoRECT sites (Philadelphia and Suffolk County, Massachusetts) are among of the 48 EHE-focused counties that seek to treat HIV rapidly and effectively to reach sustained viral suppression [29]. Findings from CoRECT suggest that this D2C strategy linked to a public health re-engagement strategy may prove beneficial to engage and re-engage the estimated 250,000 persons who are aware of their infection, but not currently receiving HIV care and treatment.

While there was no significant difference between study arms in the overall proportion of persons with viral suppression, in the era of "Undetectable=Untransmittable", it is important to focus also on shortening the time interval in which viral suppression is achieved [30]. Persons with HIV who achieve and maintain an undetectable viral load do not transmit the virus to others sexually. Thus, re-engaging newly out-of-care persons and achieving viral suppression faster can limit the opportunity for onward community transmission. In CoRECT, we found a significantly shorter time to re-engagement in all three jurisdictions.

Despite the promising outcomes observed, this study has limitations. First, all three CoRECT study sites were in the Northeast U.S. which may limit generalizability to other jurisdictions. Second, intervention delivery fidelity was not assessed and beyond the scope of this study. The public health intervention varied by site and the specific activities by DIS or field epidemiologists for each client was not assessed. The implication is that in a "real world" intervention, where delivery fidelity was not assessed it can make it more difficult to elucidate the exact factors (e.g. referrals, expedited medical appointments, ARTAS, non-monetary incentives) that led to improved re-engagement or retention in care. Third, SOC in participating HIV clinics almost certainly changed over time as study participation may have helped the sites – which were concurrently implementing the intervention – identify gaps in their procedures. It is possible that the SOC improved with respect to re-engagement procedures, with time, potentially decreasing the impact of the intervention on re-engagement. This limitation, however, may suggest that the public health intervention was more effective than reported. Fourth, structural and operational differences between the participating health departments provided some variation in the design of some elements of the study, notably the design and implementation of the active public health intervention, the effects of which could affect generalizability and account for differences in outcomes. Finally, the definition of newly out-of-care used here may only comprise a specific group that were recently out-of-care, e.g., in care for at least once during a 12-period followed by out-of-care for at least 6 months. Given this definition, it is possible that this intervention may not be effective for persons who may be out-of-care for longer periods of time. Costs and cost-effectiveness of the CoRECT intervention using primary data on intervention effectiveness and costs were obtained during the trial and analysis is ongoing.

In conclusion, the CoRECT study was a randomised controlled trial that recruited over 1800 PWH at multiple clinical sites, in three geographic areas who were identified as newly out-of-care. Utilizing a collaborative D2C strategy and implementing an active public health intervention improved re-engagement at all sites, including among high priority populations. We found an improvement in retention in care overall but did not find an improvement in viral suppression at any of the three study sites. Overall, this study provides evidence that a collaborative D2C model is an effective strategy to identify, locate, and re-engage out-of-care persons with HIV infection, including hardly reached populations.

Contributors

Robyn Neblett Fanfair: Conceptualization, Writing – original draft, Writing – review & editing. **George Khalil:** Conceptualization, Statistical analysis, Writing – original draft, Writing – review & editing. **Tiffany Williams:** Data management, Statistical analysis, Writing – original draft, Writing – review & editing. **Kathleen Brady:** Conceptualization, Writing – original draft, Writing – review & editing, Resources, Data curation. **Alfred DeMaria:** Conceptualization, Writing – original draft, Writing – review & editing, Resources, Data curation. **Merceditas Villanueva:** Conceptualization, Writing – original draft, Writing – review & editing, Resources, Data curation. **Liisa M. Randall:** Conceptualization, Writing – original draft, Writing – review & editing, Resources, Data curation. **Heidi Jenkins:** Conceptualization, Writing – original draft, Writing – review & editing, Resources, Data curation. **Frederick L. Altice:** Conceptualization, Writing – original draft, Writing – review & editing, Resources, Data curation. **Nasima Camp:** Conceptualization, Writing – original draft, Writing – review & editing. **Crystal Lucas:** Conceptualization, Writing – original draft, Writing – review & editing, Resources, Data curation. **Marianne Buchelli:** Writing – review & editing. **Taraz Samandari:** Conceptualization, Writing – original draft, Writing – review & editing. **Paul J. Weidle:** Conceptualization, Writing – original draft, Writing – review & editing.

Declaration of interests

As an academic principal investigator on several funded projects, Dr. Altice receives support from Merck Sharp & Dohme, Gilead, National Institutes of Health, National Institute on Drug Abuse, Fogarty International Center, Substance Abuse and Mental Health Services Administration and the Health Resources and Services Administration.

Data sharing statement

Individual participant data will not be shared because of data use agreements between CDC, the CoRECT clinical sites and the Philadelphia Department of Health, Connecticut Department of Health and the Massachusetts Department of Health. The study protocol, statistical analysis plan, and data dictionary are available upon request at iyo5@cdc.gov.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.lana.2021.100057.

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