Antiretroviral Adherence Following Prison Release in a Randomized Trial of the imPACT Intervention to Maintain Suppression of HIV Viremia

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Abstract

Many people living with HIV (PLWH) pass through correctional facilities each year, a large proportion of whom do not maintain viral suppression following release. We examined the effects of imPACT, an intervention designed to promote post-release viral suppression, on antiretroviral therapy (ART) adherence. PLWH awaiting release from prisons in two southern states were randomized to imPACT (consisting of motivational interviewing, care linkage coordination, and text message medication reminders) versus standard care (SC). ART adherence, measured by unannounced monthly telephone pill counts, was compared between study arms over 6 months post-release. Of 381 participants eligible for post-release follow-up, 302 (79%) completed ≥ 1 of 6 possible pill counts (median: 4; IQR 1–6). Average adherence over follow-up was 80.3% (95% CI 77.5, 83.1) and 81.0% (78.3, 83.6) of expected doses taken in the imPACT and SC arms, respectively. There was no difference between arms when accounting for missing data using multiple imputation (mean difference = − 0.2 percentage points [− 3.7, 3.3]), controlling for study site and week of follow-up. Of the 936 (40.9%) pill counts that were missed, 212 (22.7%) were due to re-incarceration. Those who missed pill counts for any reason were more likely to be unsuppressed, suggesting that they had lower adherence. However, missingness was balanced between arms. Among PLWH released from prison, ART adherence averaged > 80% in both study arms over 6 months—a level higher than seen with most other chronic diseases. However, missing data may have led to an overestimate of adherence. Factors independent of the intervention influence ART adherence in this population and should be identified to inform future targeted interventions.

Keywords HIV infection · ART adherence · Prisons · Medication adherence · Telephone pill counts

Introduction

Among people living with HIV (PLWH), antiretroviral therapy (ART) improves health outcomes including viral suppression, which directly translates to reduced rates of secondary transmission [1–3]. The potential of ART to reduce HIV transmission depends on early ART initiation and good adherence to treatment regimens once initiated [1, 2, 4]. 'Seek, Test, Treat, and Retain' (STTR) is an HIV intervention approach comprising early diagnosis, linkage to care, ART initiation, and retention in care that has the potential to substantially impact the HIV epidemic if uptake is high [5, 6].

The United States (US) correctional system is a unique setting where STTR has a particularly high potential to greatly improve health outcomes and reduce HIV transmission [7–11]. The prevalence of HIV in US prisons is substantially higher than in the general population [8, 12], and 14–17% of PLWH in the US pass through the correctional system each year [13, 14]. Prisons typically conduct routine HIV testing to identify persons with undiagnosed HIV infection, and provide free access to care and ART throughout

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the duration of incarceration [15]. Although estimates vary regarding the number of previously undiagnosed PLWH entering the correctional system [7, 12, 14–17], HIV care is initiated or re-initiated for many PLWH in this setting [15]. Consequently, an estimated 50–70% of PLWH have undetectable viral loads at the time of release from prison [9, 15, 18, 19].

For those individuals who do achieve viral suppression in prison, challenges during the transition back to the community post-release may have salient implications. Upon re-entry into the community, PLWH frequently are not linked successfully to sustained HIV care [20, 21]. Although PLWH are usually provided with short-term supplies of ART upon release from prison [13], many do not fill initial ART prescriptions after re-entry into the community [18], and individuals with a history of incarceration tend to have low adherence to prescribed ART regimens when out of prison [15, 22, 23]. These interruptions in ART mean that PLWH released from prison often do not maintain viral suppression after re-entry into the community [15, 19, 24–26], putting these individuals at risk for HIV transmission to their partners [4].

Structural factors influence the ability of individuals released from prison to connect with community HIV care, maintain ART adherence, and avoid additional contacts with the correctional system. These factors include high prevalence of untreated mental illness and substance use, unstable housing, transportation issues, and lapses in employment and health insurance coverage, as well as the compounded stigma associated with having both HIV infection and a history of incarceration [13, 27–32]. Rates of re-incarceration are high, especially among PLWH [19, 24, 25, 27]. Studies have shown that individuals with multiple periods of incarceration have worse HIV-related health outcomes, including viral non-suppression [24].

The imPACT (individuals motivated to Participate in Adherence, Care and Treatment) trial was among the first randomized trials of an intervention aiming to maintain viral suppression using the STTR approach in PLWH released from prison. The imPACT intervention was designed to specifically address multiple factors previously shown to be barriers to linkage to HIV care, retention in care, and ART adherence [33]. This multi-component, evidence-based trial was conducted in two large southern states, which combined have approximately one in seven of all individuals incarcerated in the US. Previously published results found that viral suppression did not differ between study arms, indicating no significant effect of the intervention on viral suppression following prison release, but that viral suppression declined over time [20]. Given these findings, the present study aims to examine differences in ART adherence between study arms and provide an overall assessment of adherence to ART after release from prison.

Methods

Study Participants

PLWH incarcerated within the Texas (TX) Department of Criminal Justice or North Carolina (NC) Department of Public Safety who were English-speaking, at least 18 years of age, treated with ART, virally suppressed (defined as a recorded plasma HIV RNA level of < 400 copies/mL) within 90 days prior to release, and willing and able to provide written consent were eligible for enrollment into the imPACT trial. Participants were required to (a) have had an expected prison release date within approximately 12 weeks after enrollment, and (b) not have been convicted of violent offenses (i.e., related to sexual assault, serious injury, or death) in order to minimize risk to study staff. Study screening and recruitment occurred during routine visits at prison medical clinics or in a private, secured room within the prison unit. Screening and enrollment have been described in detail previously [20]. Enrollment began in March 2012 and all study procedures were completed by February 2015.

Ethical Review

Trial procedures were approved by the institutional review boards (IRB) at Texas Christian University (TCU) and the University of North Carolina at Chapel Hill (UNC), as well as by human subjects committees at both prison systems and the US Office of Human Research Programs (OHRP). Approval for the analysis presented here was provided by the IRBs at TCU and UNC.

Study Design

The design of the imPACT trial has been described in detail previously [20, 33]. Eligible participants were randomized 1:1 to the imPACT intervention arm or standard care (SC), with randomization stratified by state. All participants received discharge planning prior to release, which included referrals to community clinics, housing arrangements, and a supply of ART as per SC—a 10-day supply in TX and 30-day supply in NC. All study participants were provided with a cell phone for unannounced ART pill counts and reminders for study follow-up visits. The main elements of the intervention included (1) two in-prison sessions of motivational interviewing with cognitive mapping and accompanying videos followed by an additional six sessions conducted by cell phone over the course of 12 weeks post-release, (2) a pre-release needs

assessment with a study Link Coordinator, who then scheduled a community clinic appointment for the participant within 5 days of release, and (3) cell phone text message reminders before each dose of ART for 12 weeks post-release.

Measures

The primary outcome of the present analysis was adherence to ART, measured using telephone pill counts over 6 months. Study staff conducted monthly unannounced cell-phone-based pill counts, which have been shown to be a valid, objective measure of ART adherence [34–36]. A baseline telephone pill count was conducted shortly after release to account for all medications. During each unannounced monthly pill count, participants were asked to count and report how many pills they had remaining in their monthly pill bottle and how many pills had been dispensed to them since the last call. The expected number of pills a participant should have had remaining that month was determined using prescription label data, including number of pills dispensed, as reported over the phone by the participant reading the label. The observed number of pills taken since the prior count was calculated as the number of counted pills subtracted from the number of pills at the prior count, adjusting for pills dispensed and any other gains and losses. Similarly, the expected number of pills taken since the prior count was calculated based on the number of intervening days and the prescribed number of pills to be taken per day. Adherence was calculated as a ratio of the observed pills taken to expected pills taken, resulting in a continuous proportion ranging from 0 to 1. At each monthly follow-up, study participants were classified as having a completed contact (a pill count was completed), re-incarcerated prior to the pill count, lost to follow-up, deceased, or a missed contact. A participant was classified as having a missed contact if there was not a pill count completed for the particular month of follow-up, but they were not lost to follow-up at that time (i.e., they had later pill counts or other study visits) or re-incarcerated.

Viral suppression, the primary outcome of the trial, was defined as a plasma HIV-1 RNA level < 50 copies/mL, measured post-release at weeks 2, 6, 14, and 24. Demographic information was collected at baseline. Psychological functioning and mental health status were collected at baseline using the modified TCU PSY Form and TCU HLTH Form, both of which have demonstrated high reliability and validity in this population [37, 38]. Prior alcohol use at baseline was measured using the Alcohol Use Disorders Identification Test (AUDIT) [39, 40] and prior drug use at baseline was measured using the TCU DSII Form [37, 41] in TX and Substance Abuse Subtle Screening Inventory (SASSI) [42] in NC. If an individual was re-incarcerated during follow-up, they were considered to be lost and no additional follow-up data was collected, including viral loads.

Analysis

We first conducted a complete-case intent-to-treat (ITT) analysis of post-release adherence to ART between arms using ordinary least squares regression with clustered standard errors for repeated observations per person, controlling for site and time since release. We also considered interactions by study site and time, examining Wald p-values for interaction terms ($p < 0.1$) and comparing stratified estimates and their 95% confidence intervals (CI). To account for nontrivial missing data, we then analyzed adherence over time between arms using multiple imputation with chained equations to impute adherence 50 times (Stata imputation code provided in Supplementary Material 1). Data were assumed to be missing at random for the imputation model. Predictors of missing pill counts that were used in the imputation model were determined using area under the receiver operating curve. The variables included in the imputation model were (in order of addition) social support (modeled as quadratic), week of follow-up, site, incarceration length, education, psychological distress, age, intervention, intimate partner violence, race and ethnicity, and sex. Other imputation models were run, varying the order of variable addition, but the order of the variables in the imputation model had a negligible effect on the model estimates. The largest Fraction of Missing Information (FMI) in the adjusted regression model using imputed data was 36% (FMI by model parameter shown in Supplementary Material 2). Re-incarceration and death were treated as competing risks, i.e., adherence measures were not imputed for time points after these events. Social support was missing for < 1% of observations, so was included as an imputed variable. All other variables had complete data for participants who did not experience competing risks.

We assessed adherence, pill count completion, and re-incarceration stratified by participant characteristics. Finally, to evaluate adherence in relation to viral suppression, we assessed pill count completion and viral suppression among participants with viral load (VL) laboratory measures at month 6 of follow-up.

Data management was completed in SAS version 9.4 (Cary, NC) and all analyses were conducted using Stata 14 (College Station, TX).

Results

Participant Characteristics

There were 1802 patients screened for the imPACT trial and of these, 1324 were ineligible and 73 declined to participate.

A total of 405 participants were enrolled and randomized in TX (n = 242) and NC (n = 163). Of the 405 eligible participants who were enrolled and randomized, 24 were withdrawn following randomization because they became ineligible, mostly due to an extension of their prison sentence or because they were newly recognized as a threat to safety of the study staff (11 from the imPACT arm and 13 from the SC arm). Among the remaining 381 participants, 195 were in the intervention arm and 186 participants in SC. Baseline characteristics were balanced between arms (Table 1). Participants were mostly black men, never married, with a median age of 43–44 years, and incarcerated < 1 year.

ART Adherence by Study Arm

Seventy-nine percent of study participants (n = 302) completed at least 1 pill count (median: 4, IQR 1–6) over 6 months of follow-up. Mean adherence (percentage of expected doses taken) across pill counts was 80.3% (95% CI 77.5, 83.1) in the imPACT arm and 81.0% (95% CI 78.3, 83.6) in the SC arm. Figure 1 shows unadjusted complete-case adherence over time in each study arm. Mean adherence at each of the 6 months of follow-up ranged from 78.5% to 84.0% in the imPACT arm and 76.6% to 84.8% in the SC arm. In the complete-case analysis

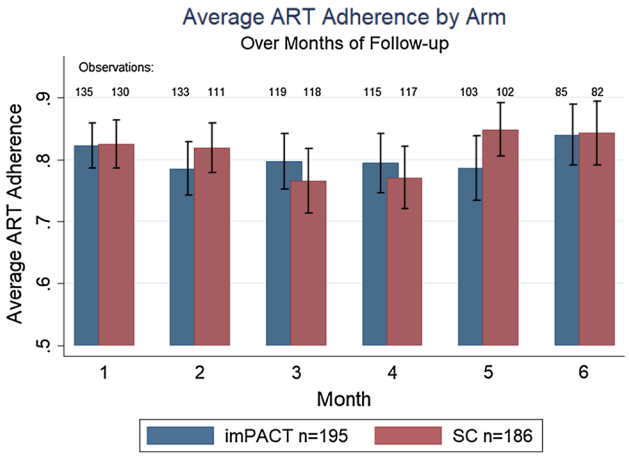

Fig. 1 Average ART adherence (95% CI) by study arm, using complete cases

controlling for site and week of follow-up (Table 2), adherence did not differ between arms (mean difference = −0.6 percentage points; 95% CI −4.4, 3.1). While overall adherence differed by study site (data not shown), no significant interactions were observed between the intervention and site or week of follow-up.

Table 1 Baseline characteristics of study participants

Characteristic	imPACT (n = 195) n (%) or median (IQR)	SC (n = 186) n (%) or median (IQR)
Age	44 (35–49)	43 (34–49)
Male sex	147 (79)	150 (77)
Race		
White	46 (24)	39 (21)
Black	121 (62)	128 (69)
Other	28 (14)	19 (10)
Hispanic ethnicity	10 (5)	17 (9)
CD4 cell count/mm^3[a]	490 (339–709)	511 (300–734)
Incarceration length (years)	0.74 (0.47–1.75)	0.81 (0.48–1.85)
Psychological distress		
Not high	129 (66)	133 (72)
High	22 (11)	24 (13)
Very high	44 (23)	29 (16)
Education		
Some high school	76 (39)	80 (43)
High school/GED	73 (37)	61 (33)
Some college/trade school	46 (24)	45 (24)
Marital status		
Married	33 (17)	24 (13)
Formerly married	47 (24)	35 (19)
Never married	115 (59)	127 (68)
History of substance use[a]	127 (68)	116 (66)

[a]Missing data: CD4 (0.3%), substance use (4%)

Table 2 Intent-to-treat comparison of average adherence by arm by (a) complete-case analysis, and (b) multiple imputation (MI) to account for missing data, controlling for site and week of follow-up

Analysis[a]	% Mean adherence (95% CI)		
	imPACT	SC	% Mean difference (95% CI)
A. Complete case[b]	81.9 (78.6, 85.1)	82.5 (78.8, 86.2)	−0.6% (−4.4, 3.1)
B. Multiple imputation	81.0 (77.5, 84.5)	81.2 (77.4, 85.0)	−0.2% (−3.7, 3.3)

[a]Adjusted for site and week of follow-up

[b]Missing data: 40.9% (n = 936) of all pill counts were missed. Missed counts due to re-incarceration or death (24.3% of missed counts) were treated as a competing risk and not imputed

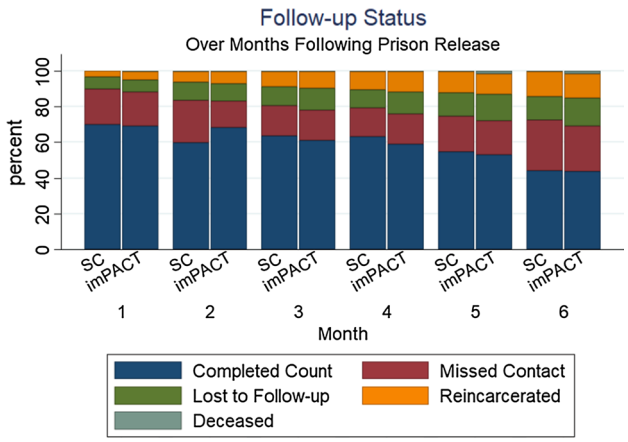

Fig. 2 Follow-up status over 6 months by study arm

Loss to follow-up and missed contacts were common. Figure 2 shows follow-up status over time by study arm. Of all participants, 67% (n = 256) were retained in the trial for 6 months, but only 44% (n = 167) of study participants completed the final pill count at 6 months post-release (Fig. 2). During study follow-up, 17% of the sample were re-incarcerated. Missed pill counts were common; 40.9% (n = 936) of all pill counts were missed at some point during follow-up. Of these, 22.7% (n = 212) were missed due to re-incarceration. Re-incarceration, loss to follow-up, and missed contacts were balanced between study arms. Participants who completed all follow-up contacts had consistently higher mean adherence throughout follow-up than participants who were missed, lost, or re-incarcerated (data not shown). Analysis of adherence over time between arms using multiple imputation to correct for missing data was consistent with the complete-case analysis, showing comparable adherence between study arms (mean difference = -0.2 percentage points; 95% CI − 3.7, 3.3), controlling for site and week of follow-up (Table 2).

Table 3 Comparison of average adherence, completion of pill counts, and re-incarceration by key covariates, using complete cases

	Average adherence (n = 381)	% Completed counts (n = 381)	% Re-incarcerated (n = 63)
Age			
20–29	79.1	59.3	14.0
30–39	81.1	48.7	18.8
40–49	79.7	61.3	20.3
50 +	82.2	67.0	9.0
Sex			
Male	80.8	59.9	16.2
Female	80.1	56.0	17.9
Race			
White non-Hispanic	81.0	54.5	15.3
Black non-Hispanic	80.4	61.3	16.1
Other non-Hispanic	81.3	55.3	21.3
Hispanic ethnicity	80.9	53.7	18.5
Incarceration length			
< 6 months	78.4	44.3	25.5
7–12 months	80.7	56.1	17.8
> 1 year	81.5	71.7	9.3
Education			
Some HS	81.7	53.6	23.7
HS Diploma/GED	77.6	59.0	13.4
Some college/trade school	83.0	68.5	8.8
Psychological distress			
Not high	79.8	63.8	10.1
High distress	81.2	51.0	12.9
Very high distress	77.6	40.8	22.8

ART Adherence, Study Follow-up, and Participant Characteristics

Average adherence was similar across most covariates (Table 3), although adherence was lowest among participants

with only a high school (HS) diploma or GED (77.6%) compared to those with less than a HS diploma/GED or with some college (81.7% and 83.0%, respectively), and among those who screened positive for very high psychological distress (77.6%) compared to participants with lower levels or no signs of distress (81.2% and 79.8%). Adherence was also lower among those incarcerated < 6 months (78.4%) than among those incarcerated 7 to < 12 months (80.7%) or ≥ 12 months (81.5%). The percentage of completed pill counts was lowest among participants age 30–39 (48.7%), those with less than a HS diploma (53.6%), those incarcerated < 6 months (44.3%), and those screening positive for very high psychological distress (40.8%). Participants of other than white or black race were most likely to be re-incarcerated (21.3%), as were those incarcerated < 6 months (25.5%), with less than a HS diploma/GED (23.7%), or very high psychological distress (22.8%). Only psychological distress and incarceration length were associated with all three outcomes (adherence, pill count completion, and re-incarceration).

Although ART adherence remained steady at approximately 80% throughout follow-up among those completing pill counts, our previously published report found that viral suppression prevalence steadily declined throughout follow-up [20]. Sixty percent and 61% of participants who completed follow-up in the imPACT (n = 128) and SC arms (n = 125) were virally suppressed at 24 weeks post-release, with no difference between arms [20]. ART adherence and VL were assessed on different schedules (final pill count in week 21, final VL in week 24) and had different patterns of missingness (so long as participants were not re-incarcerated, at which point both outcomes were censored). Therefore, we were able to assess whether viral suppression differed between those with and without missing pill counts prior to the final VL measure. Of all 253 participants with a week 24 VL, 114 (71.3%) of the 160 participants who also had a completed pill count at week 21 post-release remained virally suppressed at the end of study follow-up, compared to 41 (44.1%) of the 93 participants who did not complete the week 21 pill count but did have a week 24 VL (data not shown).

Discussion

In this randomized trial of a multi-component intervention aimed at maintaining viral suppression in PLWH released from prison, adherence to ART was relatively high, averaging above 80%, and did not differ between the imPACT and standard care arms throughout follow-up. This result is consistent with the primary outcome of the imPACT trial, which found no difference in viral suppression between arms at 6 months following release from prison [20]. When accounting for nontrivial missing data using multiple imputation, this finding of no difference between study arms held. Of note, while adherence did not differ between arms, adherence to long-term therapy in this study population was higher than has often been seen among patients with other chronic diseases [43–45]. Adherence was higher than seen in some analyses of individuals released from prison; [15, 22] however, it is not inconsistent with all studies of post-release interventions. Teixeira et al. [46] found sustained high levels of ART adherence among PLWH released from New York City Jails who received a transitional care-coordination plan upon release.

The imPACT intervention was an evidence-based intervention designed to enhance motivation to enter community-based HIV care and support linkage to care and ART adherence [33]. The design was based on extensive evidence of challenges that PLWH released from prison face upon re-entry into the community, using a multi-component design to simultaneously address multiple factors that hinder care access and ART adherence among recently released PLWH. The similarity in adherence between study arms suggests that additional factors not adequately addressed by the intervention influence ART adherence following prison release. Identifying and addressing additional factors that contribute to adherence, HIV care engagement, and attrition may further improve prison-to-community linkage to care, ART adherence, and rates of viral suppression following community re-entry.

Previous studies have found that psychological comorbidity negatively impacts ART adherence among PLWH [47, 48], including those with a history of incarceration [30]. This is consistent with our finding of lower-than-study-average adherence among individuals with high psychological distress. An analysis by Montague et al. [49] of linkage to care among PLWH released from correctional facilities found that individuals who had been incarcerated > 6 months had a shorter time to care linkage after release than those with a shorter period of incarceration. In that study, the authors hypothesized that during longer incarceration periods, individuals may receive education, more discharge planning, and medical stabilization that then may influence linkage to care upon release. Similarly, Baillargeon et al. [18]. found that individuals with longer duration of incarceration (≥ 1 year) were more likely to fill an ART prescription shortly after prison release than those who had been in prison < 1 year. In this study, individuals with longer duration of incarceration were more likely to have received help with their applications for drug assistance. The findings from these studies are consistent with our finding that adherence to ART was lower among individuals incarcerated < 6 months.

Previously published results from this trial show that despite consistently high adherence, participants in both study arms who completed follow-up VL testing experienced

a steady loss of viral suppression in the 6 months following prison release [20]. This apparent inconsistency may be due in part to greater capture of VL data than pill count data in the full study population, along with the likelihood that those with missing pill count data were likely to have lower-than-average adherence. Compared to participants without missing pill counts, those with missing counts exhibited lower adherence when they were still active in the study, suggesting that our complete-case analysis overestimated adherence in the full study population. The complete-case analysis of VL data may have been less susceptible to overestimation, as viral non-suppression among at least some of those with missing pill count data was captured. We additionally note that the similarity of results between our complete-case and multiple imputation analyses of adherence suggests that observed factors alone may not be sufficient to accurately impute missing adherence values.

All study participants received a cell phone for study contact purposes and engaged in regular contact with study staff, including appointment reminders and unannounced monthly pill counts. Cell phone provision and regular contact with study staff may have acted as an intervention in the SC arm by providing support and motivation to the study participants, and in this way may have helped these participants overcome some of the destabilizing effects of prison release and community re-entry in order to maintain good ART adherence. Prior research has shown that cell phones provided to women with substance use and depression may assist with linkage to services after release from prison [50]. The main findings from the imPACT trial also demonstrated that overall attendance at HIV care appointments was similar between arms [20], which may be partially explained by cell phone provision and regular contact by study staff in both study arms.

The number of individuals lost to study follow-up was high, but unsurprising based on other studies in similar populations [21, 46]. Re-incarceration was the most common reason for loss to follow-up in this study population, with close to one-fifth of the study population re-incarcerated during follow-up, accounting for a large portion of missed pill counts. This level of re-incarceration is consistent with previous studies [22, 23, 25, 27], which have demonstrated that many individuals who come into contact with the US correctional system experience a "revolving door" effect, with frequent re-incarceration events [27, 51]. Similar to other studies among persons released from US prisons, re-incarceration in this study was most common among less educated individuals [52] and those with evidence of psychological distress [25, 53]. Individuals who did not complete follow-up were also less adherent to ART before they were lost.

Several study limitations should be considered when interpreting the results of this analysis. First, as previously discussed, there was a large amount of missing data due to missed contacts, re-incarceration, and loss to follow-up, with two-fifths of pill counts missed. However, missing data was balanced between arms, and analyses using multiple imputation to account for these missing data supported findings from the complete-case analysis of no difference between arms. Unmeasured factors are likely associated with missing adherence measures (i.e., non-ignorable missing data) and therefore the underlying assumption of data missing at random for our imputation model may not be met. This non-ignorable missingness potentially contributes to the inconsistent trial results of decline in viral suppression over follow-up despite consistently high ART adherence. Second, unannounced monthly pill counts, while a valid and reliable measure of adherence, may be an imperfect measure of ART adherence because counts cannot be visually confirmed [34–36]. Third, cell phone provision to both study arms may have affected medication adherence in the SC arm, and the monthly research study phone contacts for pill counts may have acted as an intervention in their own right. Finally, this analysis was conducted in only two state prison systems and the study population was mostly male. While these two states account for more than 1 in 7 members of the incarcerated population in the US, the results of this analysis may not be generalizable to the larger US population of PLWH released from prison.

Conclusions

In conclusion, overall ART adherence in this population of PLWH newly released from prison was high, averaging over 80% through 6 months following release. However, missing data may have led to an overestimate of adherence. There was no difference in ART adherence between the imPACT and SC arms even when accounting for missing data, indicating that there are factors not adequately addressed by the intervention that influence ART adherence following release from prison in this population. Cell phone provision and monthly pill counts may have acted as an intervention in the SC arm and could partially explain our findings of no difference between study arms. Given high rates of re-incarceration, a continued focus on creating a continuum of care between prison correctional facilities and community HIV care is crucial to address ART adherence and loss of viral suppression among PLWH re-entering the community after prison release.

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Authors Contribution CEG, KK, PMF, and DAW contributed to acquisition of the data. JSG assisted with data management. BWP, CEG, SN and DAW conceived of the analysis. BLD and BWP designed and completed the analysis. BLD drafted the manuscript. BWP, CEG, KK, PMF, JCA, JSG, KAP, BLW, SN, and DAW assisted with the interpretation of the data and critically revised the manuscript for important intellectual content. The authors thank the TDCJ (including Allyson Glass, Scott Edmiston, Valla Kirby-Brossman; Frances Gattis; April Scott; Courtney Ross; Mandy Vance) and the NCDPS (including Paula Smith, Pamela Gibbs), particularly the discharge planning and clinic staff, as well as the participants for their generous contribution. We also thank the trial research staff including: *UNC* - Lisa McKeithan, Steve Bradley-Bull, Kemi Amola, Lynn Tillery, Makisha Ruffin, Angela Edwards, Katesha Peele, Neeve Neevel, Madeline McCrary, Elizabeth Roberts, Erika Hallback, and Sayaka Hino; *TCU* - Roxanne Muiruri, Molly McFatrich, Julie Gray, Scott Edmiston, Allyson Glass, Courtney Ross, Mandy Vance, Valla Kirby-Brossman, Elizabeth Larios, Laurence Misedah, and Bethany Evans.

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Compliance with Ethical Standards

Conflicts of interest The authors have no conflicts of interest to declare.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

References

1. Cohen MS, Smith MK, Muessig KE, Hallett TB, Powers KA, Kashuba AD. Antiretroviral treatment of HIV-1 prevents transmission of HIV-1: where do we go from here? Lancet. 2013;382(9903):1515–24.
2. Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011;365(6):493–505.
3. Donnell D, Baeten JM, Kiarie J, et al. Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. Lancet. 2010;375(9731):2092–8.
4. Skarbinski J, Rosenberg E, Paz-Bailey G, et al. Human immunodeficiency virus transmission at each step of the care continuum in the United States. JAMA Intern Med. 2015;175(4):588–96.
5. Granich RM, Gilks CF, Dye C, De Cock KM, Williams BG. Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model. Lancet. 2009;373(9657):48–57.
6. Gardner EM, McLees MP, Steiner JF, Del Rio C, Burman WJ. The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. Clin Infect Dis. 2011;52(6):793–800.
7. Elkington KS, Jaiswal J, Spector AY, et al. Can TasP approaches be implemented in correctional settings?: a review of HIV testing and linkage to community HIV treatment programs. J Health Care Poor Underserved. 2016;27(2A):71–100.
8. Wohl DA. HIV and mass incarceration: where infectious diseases and social justice meet. N C Med J. 2016;77(5):359–64.
9. Meyer JP, Cepeda J, Wu J, Trestman RL, Altice FL, Springer SA. Optimization of human immunodeficiency virus treatment during incarceration: viral suppression at the prison gate. JAMA Intern Med. 2014;174(5):721–9.
10. Lima VD, Graf I, Beckwith CG, et al. The impact of implementing a test, treat and retain HIV prevention strategy in atlanta among black men who have sex with men with a history of incarceration: a mathematical model. PLoS ONE. 2015;10(4):e0123482.
11. Beckwith C, Bazerman L, Gillani F, et al. The feasibility of implementing the HIV seek, test, and treat strategy in jails. AIDS Patient Care STDS. 2014;28(4):183–7.
12. Wohl DA, Golin C, Rosen DL, May JM, White BL. Detection of undiagnosed HIV among state prison entrants. JAMA. 2013;310(20):2198–9.
13. Rich JD, DiClemente R, Levy J, et al. Correctional facilities as partners in reducing HIV disparities. J Acquir Immune Defic Syndr. 2013;63(Suppl 1):S49–53.
14. Spaulding AC, Seals RM, Page MJ, Brzozowski AK, Rhodes W, Hammett TM. HIV/AIDS among inmates of and releasees from US correctional facilities, 2006: declining share of epidemic but persistent public health opportunity. PLoS ONE. 2009;4(11):e7558.
15. Iroh PA, Mayo H, Nijhawan AE. The HIV care cascade before, during, and after incarceration: a systematic review and data synthesis. Am J Public Health. 2015;105(7):e5–16.
16. Seth P, Figueroa A, Wang G, Reid L, Belcher L. HIV testing, HIV positivity, and linkage and referral services in correctional facilities in the United States, 2009–2013. Sex Transm Dis. 2015;42(11):643–9.
17. VanHandel M, Beltrami JF, MacGowan RJ, Borkowf CB, Margolis AD. Newly identified HIV infections in correctional facilities, United States, 2007. Am J Public Health. 2012;102(Suppl 2):S201–4.
18. Baillargeon J, Giordano TP, Rich JD, et al. Accessing antiretroviral therapy following release from prison. JAMA. 2009;301(8):848–57.
19. Meyer JP, Cepeda J, Springer SA, Wu J, Trestman RL, Altice FL. HIV in people reincarcerated in Connecticut prisons and jails: an observational cohort study. Lancet HIV. 2014;1(2):e77–84.
20. Wohl DA, Golin CE, Knight K, et al. Randomized controlled trial of an intervention to maintain suppression of HIV viremia after prison release: the imPACT trial. J Acquir Immune Defic Syndr. 2017;75(1):81–90.
21. Althoff AL, Zelenev A, Meyer JP, et al. Correlates of retention in HIV care after release from jail: results from a multi-site study. AIDS Behav. 2013;17(2):156–70.
22. Palepu A, Tyndall MW, Chan K, Wood E, Montaner JS, Hogg RS. Initiating highly active antiretroviral therapy and continuity of HIV care: the impact of incarceration and prison release

on adherence and HIV treatment outcomes. Antivir Ther. 2004;9(5):713–9.
23. Meyer JP, Zelenev A, Wickersham JA, Williams CT, Teixeira PA, Altice FL. Gender disparities in HIV treatment outcomes following release from jail: results from a multicenter study. Am J Public Health. 2014;104(3):434–41.
24. Springer SA, Pesanti E, Hodges J, Macura T, Doros G, Altice FL. Effectiveness of antiretroviral therapy among HIV-infected prisoners: reincarceration and the lack of sustained benefit after release to the community. Clin Infect Dis. 2004;38(12):1754–60.
25. Baillargeon J, Giordano TP, Harzke AJ, et al. Predictors of reincarceration and disease progression among released HIV-infected inmates. AIDS Patient Care STDS. 2010;24(6):389–94.
26. Loeliger KB, Meyer JP, Desai MM, Ciarleglio MM, Gallagher C, Altice FL. Retention in HIV care during the 3 years following release from incarceration: a cohort study. PLoS Med. 2018;15(10):e1002667.
27. Fu JJ, Herme M, Wickersham JA, et al. Understanding the revolving door: individual and structural-level predictors of recidivism among individuals with HIV leaving jail. AIDS Behav. 2013;17(Suppl 2):S145–55.
28. Westergaard RP, Spaulding AC, Flanigan TP. HIV among persons incarcerated in the USA: a review of evolving concepts in testing, treatment, and linkage to community care. Curr Opin Infect Dis. 2013;26(1):10–6.
29. Haley DF, Golin CE, Farel CE, et al. Multilevel challenges to engagement in HIV care after prison release: a theory-informed qualitative study comparing prisoners' perspectives before and after community reentry. BMC Public Health. 2014;14:1253.
30. Dennis AC, Barrington C, Hino S, Gould M, Wohl D, Golin CE. "You're in a world of chaos": experiences accessing HIV care and adhering to medications after incarceration. J Assoc Nurses AIDS Care. 2015;26(5):542–55.
31. Loeliger KB, Altice FL, Desai MM, Ciarleglio MM, Gallagher C, Meyer JP. Predictors of linkage to HIV care and viral suppression after release from jails and prisons: a retrospective cohort study. Lancet HIV. 2018;5(2):e96–106.
32. Booker CA, Flygare CT, Solomon L, et al. Linkage to HIV care for jail detainees: findings from detention to the first 30 days after release. AIDS Behav. 2013;17(Suppl 2):S128–36.
33. Golin CE, Knight K, Carda-Auten J, et al. Individuals motivated to participate in adherence, care and treatment (imPACT): development of a multi-component intervention to help HIV-infected recently incarcerated individuals link and adhere to HIV care. BMC Public Health. 2016;16:935.
34. Fredericksen R, Feldman BJ, Brown T, et al. Unannounced telephone-based pill counts: a valid and feasible method for monitoring adherence. AIDS Behav. 2014;18(12):2265–73.
35. Kalichman SC, Amaral C, Swetsze C, et al. Monthly unannounced pill counts for monitoring HIV treatment adherence: tests for self-monitoring and reactivity effects. HIV Clin Trials. 2010;11(6):325–31.
36. Kalichman SC, Amaral CM, Cherry C, et al. Monitoring medication adherence by unannounced pill counts conducted by telephone: reliability and criterion-related validity. HIV Clin Trials. 2008;9(5):298–308.
37. Simpson DD, Joe GW, Knight K, Rowan-Szal GA, Gray JS. Texas Christian University (TCU) short forms for assessing client needs and functioning in addiction treatment. J Offender Rehabil. 2012;51(1–2):34–56.
38. Rowan-Szal GA, Joe GW, Bartholomew NG, Pankow J, Simpson DD. Brief trauma and mental health assessments for female offenders in addiction treatment. J Offender Rehabil. 2012;51(1–2):57–77.
39. Bohn MJ, Babor TF, Kranzler HR. The alcohol use disorders identification test (AUDIT): validation of a screening instrument for use in medical settings. J Stud Alcohol. 1995;56(4):423–32.
40. Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the alcohol use disorders identification test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption–II. Addiction. 1993;88(6):791–804.
41. Peters RH, Greenbaum PE, Steinberg ML, et al. Effectiveness of screening instruments in detecting substance use disorders among prisoners. J Subst Abuse Treat. 2000;18(4):349–58.
42. Rounds-Bryant JL, Baker L Jr. Substance dependence and level of treatment need among recently-incarcerated prisoners. Am J Drug Alcohol Abuse. 2007;33(4):557–61.
43. Krass I, Schieback P, Dhippayom T. Adherence to diabetes medication: a systematic review. Diabet Med. 2015;32(6):725–37.
44. De Vera MA, Marcotte G, Rai S, Galo JS, Bhole V. Medication adherence in gout: a systematic review. Arthritis Care Res. 2014;66(10):1551–9.
45. World Health Organization. Adherence to long-term therapies: evidence for action. Geneva: World Health Organization; 2003.
46. Teixeira PA, Jordan AO, Zaller N, Shah D, Venters H. Health outcomes for HIV-infected persons released from the New York City jail system with a transitional care-coordination plan. Am J Public Health. 2015;105:351–7.
47. Mugavero M, Ostermann J, Whetten K, et al. Barriers to antiretroviral adherence: the importance of depression, abuse, and other traumatic events. AIDS Patient Care STDs. 2006;20(6):418–28.
48. Gonzalez JS, Batchelder AW, Psaros C, Safren SA. Depression and HIV/AIDS treatment nonadherence: a review and meta-analysis. J Acquir Immune Defic Syndr. 2011. https://doi.org/10.1097/QAI.0b013e31822d490a.
49. Montague BT, Rosen DL, Sammartino C, et al. Systematic assessment of linkage to care for persons with HIV released from corrections facilities using existing datasets. AIDS Patient Care STDS. 2016;30(2):84–91.
50. Johnson JE, Williams C, Zlotnick C. Development and feasibility of a cell phone-based transitional intervention for women prisoners with comorbid substance use and depression. Prison J. 2015;95(3):330–52.
51. Baillargeon J, Penn JV, Knight K, Harzke AJ, Baillargeon G, Becker EA. Risk of reincarceration among prisoners with co-occurring severe mental illness and substance use disorders. Adm Policy Ment Health. 2010;37(4):367–74.
52. Marlow E, White MC, Tulsky JP, Estes M, Menendez E. Recidivism in HIV-infected incarcerated adults: influence of the lack of a high school education. J Urban Health. 2008;85(4):585–95.
53. Baillargeon J, Binswanger IA, Penn JV, Williams BA, Murray OJ. Psychiatric disorders and repeat incarcerations: the revolving prison door. Am J Psychiatry. 2009;166(1):103–9.

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