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Moderation Analysis of a couple-based HIV/STI Intervention Among Heterosexual Couples in the Criminal Legal System Experiencing Intimate Partner Violence: Results from a Randomized Controlled Trial

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Abstract

Since the COVID-19 pandemic, intimate partner violence (IPV) rates have increased in the United States. Although accumulating research has documented the effectiveness of couple-based interventions in reducing HIV/STIs, it remains unclear whether they are effective and safe for couples experiencing IPV. We used moderation analysis from a randomized clinical trial to evaluate whether a couples-based HIV/STI intervention may have differential effectiveness in reducing HIV/STI risks among couples where one or both partners reported experiencing IPV compared to couples without such IPV among a sample of 230 men at risk for HIV/STIs who reported using drugs and were mandated to community supervision settings in New York City and their main female sexual partners. The findings of this study suggest that the effectiveness of this evidence-based couple HIV intervention in reducing condomless sex and other HIV/STI risks did not differ between couples with IPV compared to couples without IPV. Intimate partners who use drugs and are involved in the criminal legal system are disproportionately impacted by both HIV/STIs and IPV, underscoring the importance of couple-level interventions that may be scaled up to address the dyadic HIV risks and IPV together in community supervision settings.

Keywords HIV · Couples · Community supervision · IPV · Drug use

Introduction

Accumulating research, including systematic reviews, have documented the efficacy of couple-level HIV interventions for at-risk populations, including people who use or inject drugs, individuals involved in the criminal legal system, and HIV sero-discordant couples [1–4]. However,

many couple-based HIV intervention studies have excluded couples with severe Intimate Partner Violence (IPV) out of concern that dyadic approaches may exacerbate violence among couples who are experiencing IPV. Nevertheless, the high prevalence of IPV in couples at risk of HIV and the strong associations between IPV and HIV/STIs [5–7] suggest the potential promise of couple-level interventions. However, research has yet to examine whether couple-level HIV interventions are effective among couples experiencing IPV, especially in the United States.

In the United States, IPV among couples has increased over the past two decades, and in 2015, about one-third of men (33.6%) and women (36.4%) reported experiencing IPV [8]. Men and women who use drugs and are involved in the criminal legal system in the United States have disproportionately high rates of IPV and HIV infection [9, 10]. Individuals involved in the criminal legal system who use drugs have the second-highest lifetime risk of becoming HIV positive, exceeded only by men who have sex with

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men (MSM) [1, 3, 9]. This is of particular concern because the number of annual HIV diagnoses among that population have increased [11] while there has been a slight decrease in the number of Black individuals involved in the criminal legal system [12].

Furthermore, many studies have found that couples who use drugs and alcohol disproportionately experience mutual IPV and are at risk of acquiring HIV, which heightens other risk behaviors, including risky sexual behaviors and substance misuse [13]. For example, a prior study found that 31% of the women who used drugs have reported experiencing mutual IPV within the previous year [14]. Racial and ethnic disparities exist in both IPV and HIV rates in the United States. Black women are disproportionately impacted by both HIV and IPV risk—the latter in particular [15, 16].

Gaps in the Literature

Despite successes in IPV and HIV behavioral prevention efforts, research is limited regarding couple-based interventions that address both IPV and HIV risk [17]. Several gaps persist in research examining the mutual IPV risk environment and HIV risk reduction among men involved in the criminal legal system in heterosexual intimate partnerships where substance use is also a factor. First, populations involved in the criminal legal system are underrepresented in research on factors of IPV that are also associated with HIV risk in the United States [18]. Second, research on HIV prevention neglects risk factors that disproportionately impact couples involved in the criminal legal system and couples who use drugs, namely IPV. Lastly, little is known about how couples who experience bi-directional IPV correlate to the extent to which intimate partners can exercise core skills of HIV risk reduction, including sexual risk communication and negotiation skills. In other words, the bi-directional nature of interactions is seldom quantified. Investigating the associations between couples' IPV and HIV risk factors could inform future HIV and IPV prevention interventions to address the unique risk factors facing couples in the United States who are involved in the criminal legal system and use drugs.

Based on a review of the CDC's best-evidence HIV risk reduction interventions, only 5 out of 44 interventions have IPV-related content and tangible strategies [19]. The definition of IPV, study measurements, and reporting guidelines used in these interventions also differed by study, which increased the challenge of comparing outcomes and drawing any conclusions regarding the effectiveness of each intervention [19]. Furthermore, although HIV couple-based interventions have demonstrated effectiveness

in reducing HIV risks among different populations, it is unknown whether HIV couple interventions are feasible, safe, and effective among couples experiencing IPV. Using couple-based approaches to reduce IPV behaviors remains controversial due to physical, sexual, and emotional safety concerns [5].

The criminal legal system is widely regarded as having higher rates of intimate partner perpetration and victimization underscoring the urgency of research investigating the role of intimate partner violence in shaping the effects of couple-oriented HIV prevention approaches [20–22]. Prior studies have found greater rates of sexual and physical trauma endured during childhood and adulthood among incarcerated populations that intersects with violence within the contexts of intimate partnerships to further heighten risk of HIV and other infectious diseases [23–25]. Involvement in the criminal legal system is largely a product of systemic failures and marginalization from social determinants of health resulting in higher rates of poverty, co-occurring mental health conditions and greater need for social services [26–28]. Intimate partners in the criminal legal system face unique issues that compound existing challenges to practicing HIV prevention consisting of disruptions to financial, emotional and other kinds of social support [29–31]. For couples in which at least one intimate partner is under community supervision, partners couples-focused research is critically needed in the criminal legal settings [29], to identify novel strategies of enhancing HIV prevention for a population with rates that significantly exceed the general population.

Couple-oriented approaches that safely and effectively address both IPV and HIV risks may hold promise for the large number of couples involved in the criminal legal system where one or both partners use drugs and are at elevated risk for both IPV and HIV/STIs. We conducted a randomized clinical trial to evaluate the effectiveness of a couple-based HIV/STI prevention intervention (PACT) among 230 men in community supervision programs who use drugs and their female intimate partners. This study found that couples who received PACT significantly reduced the number of condomless sex acts and other risk behaviors compared to couples assigned to the treatment-as-usual individual HIV testing and counseling control condition. Using data from this clinical trial, we conducted a moderation analysis to test whether the PACT intervention had differential effectiveness in reducing condomless sex and other HIV risks over a 12-month follow up period among couples with an IPV history compared to couples without such IPV. Formally, inferential statistics will test the hypothesis that IPV history will moderate the effectiveness of PACT on the primary outcome of reducing condomless intercourse or the secondary outcomes of reducing the number of sex partners, and

increasing condom use intentions, self-efficacy, and HIV communication.

Methods

This randomized controlled trial was conducted between July 11, 2013, and May 17, 2016. We used longitudinal data from a randomized clinical trial of Project PACT, a couple-focused HIV/STI prevention intervention of males with a substance-use history recruited from community supervision in New York City and their main female sexual partner [3]. We have described detailed methods, sample characteristics, the randomization plan, and the study flow chart (CONSORT diagram) elsewhere [3]. All participants completed the informed consent, and all study activities were approved by the Institutional Review Board at Columbia University.

Recruitment and Eligibility

Research assistants recruited participants from Community Correction Provider (CCP) locations in New York City [3]. Participants who consented were screened to determine eligibility. Couples were eligible to participate in the study if each of the following criteria were met: (1) Both partners were aged 18 or older; (2) Both partners identified each other as their primary sexual partner of the opposite sex; 3) The relationship had lasted at least 3 months; 4) At least one partner reported having had condomless vaginal and/or anal intercourse with the other in the past 90 days; 5) At least one partner reported exposure to an outside HIV risk in the past year (engaged in unprotected sex with another partner, shared syringes, tested positive for an HIV/STI) or at least one partner suspected that their partner had exposure to an outside HIV risk; 6) The couple planned to stay together for at least another year; 7) The male partner reported either (a) use of illicit drugs or binge drinking (i.e., drinking five or more alcoholic beverages on a single occasion) in the past 90 days or (b) attended substance abuse treatment in the past 90 days; and 8) The male partner was mandated to community supervision, alternative to incarceration, or probation verified by court records. Participants were ineligible if they could not complete the informed consent process due to a lack of English proficiency or had cognitive or psychiatric impairment. We also excluded 27 participants who reported having an order of protection against or felt unsafe completing the intervention with their partner, did not have an address to receive mail, or lived more than 90 min from New York City [3]. Assessments were performed at baseline, three, six, and 12-month follow-up post-intervention. Participants were reimbursed up to $265 for completing assessments and intervention sessions. More details on participant recruitment and retention are available in Fig. 1 and described in prior publications [1, 3].

Randomization

We randomly assigned couples to one of two study conditions. We used a computer-generated randomization algorithm to balance the number of couples per study arm via an adaptive, biased-coin procedure [3]. The treatment assignment was masked to the investigators until the final 12-month follow-up assessment was completed in July 2017. Data were locked in September 2017, after which study arms were unmasked. There were no significant differences at $p < 0.05$ level on sociodemographic variables and baseline indicators of primary and secondary outcomes among couples assigned to PACT and couples assigned to the control condition except for age, as reported elsewhere [3].

Intervention and Control Conditions

PACT Intervention:

The PACT intervention is guided by motivational interviewing skills [32], social cognitive theory [33], and an ecological framework [34]. The intervention sessions were two hours long and delivered in real-world community supervision program settings. Table 1 contains the core elements of the intervention: (1) couple-based HIV Counseling Testing and Referral (CTR); (2) disclosure of drug and sexual risks; (3) couple communication, negotiation, and problem-solving skills to reduce drug and sexual risks; (4) technical condom use skills; (5) strategies for reducing unsafe injections; (6) biomedical HIV prevention strategies, such as HIV treatment as prevention, Post-Exposure Prophylaxis (PEP), and Pre-exposure Prophylaxis (PrEP); (7) linkage to HIV, STI, and substance use treatment; (8) reproductive health issues; (9) risks and experiences of sexual coercion; (10) risks for opioid overdose; 11) informal social support; and 12) couple goal-setting to reduce long-term HIV risks [3].

Control Intervention:

The HIV control (CTR) condition consisted of individual rapid HIV/STI testing with pre- and post-test counseling and one 45-minute session that included referrals to HIV/STI treatment and other social services. The HIV CTR served as a feasible, cost-effective comparison condition [3] representing usual care.

Fig. 1 Core Elements of PACT Intervention

5 Risk Reduction Sessions with HIV Rapid CTR for PACT	1 HIV Rapid CTR Plus Service Referral Session for Control Condition
1. Individualized health risk assessment, Rapid HIV Oral Testing, and pre- post-test counseling and referral to care (CTR) 2. Disclosure of drug risk and sexual risk 3. Couple communication skills to enhance understanding and commitment to healthier choices as a dyad 4. Condom technical skills and addressing barriers to use and access female and male condoms 5. Identifying and reducing personal risks associated with drug use, including HIV risk of sharing syringes and decision-making about protected sex and medication adherence 6. Options for biomedical HIV prevention strategies, including HIV treatment as prevention, PEP, and PrEP 7. Linkage to HIV, STI, and substance use treatment 8. Reproductive health issues 9. Risks and experiences of sexual coercion 10 Overdose (OD) response and prevention, including knowledge and skills to utilize naloxone 11. Social support Enhancement for Risk Reduction – Identifying and setting goals to strengthen support from family and friends for risk reduction 12. Goal setting to increase protective behaviors (HIV testing, ART, and PrEP adherence) and to decrease risky behaviors for HIV/STIs and overdose	1. Individualized health risk assessment, Rapid HIV Oral Testing, and pre- post-test counseling and linkage to care 2. Current utilization of case management services identified and need for additional social and health services elicited 3. Resource manual provided to assist in linkage to services as identified by the couple

Measures

The IPV and HIV risk assessment questions were worded to focus on the participant's relationship with their primary sexual partner. Questions referred to "your study partner," for example: Has your study partner kicked you, slammed you against a wall, beaten you up, punched you or kicked you, hit you with something that could hurt, burn or scald you on purpose?

Demographic Variables

Self-report data were collected as follows: marital status (single, never married), sex (male/female), race and ethnicity, years of education, employment, monthly income, homelessness, type of community correction setting enrolled in the past 90 days, and criminal legal history (arrested and/or incarcerated in jail or prison) in the past 90 days.

IPV Measures:

Experience and perpetration of IPV were assessed using a 16-item questionnaire with categorical variables measuring IPV based on the Revised Conflict Tactics Scale (CTS2) [35], which has been used extensively. This dyadic inversion includes three subscales measuring any experience or perpetration of physical, sexual, and severe physical/injurious/sexual abuse. The couple's report of IPV history was defined as whether participants or their partners reported any history of perpetrating or experiencing IPV. To ascertain an experience of IPV, questions were asked in the following manner: "Has your study partner ever twisted your arm, or thrown something at you that could hurt, or pushed grabbed or slapped you, against your will?" To assess perpetration of each item, "Has your study partner" was replaced with "have you." For example: "Have you ever twisted your arm, or thrown something at you that could hurt, or pushed grabbed or slapped you, against your will?"

Table 1 Descriptive Statistics for the Couple Reports of the History of IPV at the Baseline Assessment for the Total Sample (N=460) and by Condition Assignment

	Combine perpetrating and experiencing IPV				Perpetrating IPV				Experiencing IPV			
	Total	HIV CTR (n=230)	PACT (n=228)[a]	χ² test	Total	HIV CTR (n=230)	PACT (n=228)[a]	χ² test	Total	HIV CTR (n=230)	PACT (n=228)[a]	χ² test
Any Physical, injurious or sexual IPV												
Neither	152 (33.2%)	76 (33.0%)	76 (33.3%)	χ²=0.004 (p=0.947)	200 (43.7%)	90 (39.1%)*	110 (48.2%)*	χ²=3.87 (p=0.049)	204 (44.5%)	112 (48.7%)	92 (40.4%)	χ²=3.23 (p=0.072)
Any	306 (66.8%)	154 (67.0%)	152 (66.7%)		258 (56.3%)	140 (60.9%)*	118 (51.8%)*		254 (55.5%)	118 (51.3%)	136 (59.6%)	
Male only	92 (20.1%)	52 (22.6%)	40 (17.5%)		98 (21.4%)	54 (22.5%)	44 (19.3%)		90 (19.7%)	46 (20.0%)	44 (19.3%)	
Female only	84 (18.3%)	28 (12.2%)	56 (24.6%)		90 (19.7%)	40 (17.4%)	50 (21.9%)		82 (17.9%)	28 (12.2%)	54 (23.7%)	
Both	130 (28.4%)	74 (32.2%)	56 (24.6%)		70 (15.3%)	46 (20.0%)	24 (10.5%)		82 (17.9%)	44 (19.1%)	38 (16.7%)	
Physical IPV												
Neither	238 (52.0%)	120 (52.2%)	118 (51.7%)	χ²=0.01 (p=0.928)	278 (60.7%)	126 (54.8%)**	152 (66.7%)**	χ²=6.78 (p=0.009)	276 (60.3%)	150 (65.2%)*	126 (55.3%)*	χ²=4.74 (p=0.030)
Any	220 (48.0%)	110 (47.8%)	110 (48.3%)		180 (39.3%)	104 (45.2%)**	76 (33.3%)**		182 (39.7%)	80 (34.8%)*	102 (44.7%)*	
Male only	62 (13.5%)	34 (14.8%)	28 (12.3%)		60 (13.1%)	40 (17.4%)	20 (8.8%)		56 (12.2%)	24 (10.4%)	32 (14.0%)	
Female only	82 (17.9%)	30 (13.0%)	52 (22.8%)		80 (17.5%)	38 (16.5%)	42 (18.4%)		66 (14.4%)	22 (9.6%)	44 (19.3%)	
Both	76 (16.6%)	46 (20.0%)	30 (13.2%)		40 (8.7%)	26 (11.3%)	14 (6.1%)		60 (13.1%)	34 (14.8%)	26 (11.4%)	
Injurious IPV												
Neither	422 (92.1%)	210 (91.3%)	212 (93.0%)	χ²=0.45 (p=0.505)	436 (95.2%)	212 (92.2%)**	224 (98.3%)**	χ²=9.23 (p=0.002)	434 (94.8%)	220 (95.7%)	214 (93.9%)	χ²=0.74 (p=0.389)
Any	36 (7.9%)	20 (8.7%)	16 (7.0%)		22 (4.8%)	18 (7.8%)**	4 (1.8%)**		24 (5.2%)	10 (4.4%)	14 (6.1%)	
Male only	18 (3.9%)	12 (5.2%)	6 (2.6%)		12 (2.6%)	12 (5.2%)	0 (0%)		12 (2.6%)	6 (2.6%)	6 (2.6%)	
Female only	16 (3.5%)	6 (2.6%)	10 (4.4%)		10 (2.2%)	6 (2.6%)	4 (1.8%)		12 (2.6%)	4 (1.7%)	8 (3.5%)	
Both	2 (0.4%)	2 (0.9%)	0 (0%)		0 (0%)	0 (0%)	0 (0%)		0 (0%)	0 (0%)	0 (0%)	
Sexual IPV												
Neither	248 (54.2%)	118 (51.3%)	130 (57.0%)	χ²=1.51 (p=0.220)	306 (66.8%)	140 (60.9%)**	166 (72.8%)**	χ²=7.36 (p=0.007)	302 (65.9%)	154 (67.0%)	148 (64.9%)	χ²=0.21 (p=0.644)
Any	210 (45.9%)	112 (48.7%)	98 (43.0%)		152 (33.2%)	90 (39.1%)**	62 (27.2%)**		156 (34.1%)	76 (33.0%)	80 (35.1%)	
Male only	98 (21.4%)	56 (24.4%)	42 (18.4%)		92 (20.1%)	50 (21.7%)	42 (18.4%)		82 (17.9%)	46 (20.0%)	36 (15.8%)	
Female only	60 (13.1%)	24 (10.4%)	36 (15.8%)		40 (8.7%)	24 (10.4%)	16 (7.0%)		60 (13.1%)	20 (8.7%)	40 (17.5%)	
Both	52 (11.4%)	32 (13.9%)	20 (8.8%)		20 (4.4%)	16 (7.0%)	4 (1.8%)		14 (3.1%)	10 (4.4%)	4 (1.8%)	
Psychological IPV												
Neither	204 (44.5%)	104 (45.2%)	100 (43.9%)	χ²=0.09 (p=0.770)	254 (55.5%)	124 (53.9%)	130 (57.0%)	χ²=0.45 (p=0.504)	232 (50.7%)	120 (52.2%)	112 (49.1%)	χ²=0.43 (p=0.514)
Any	254 (55.5%)	126 (54.8%)	128 (56.1%)		204 (44.5%)	106 (46.1%)	98 (43.0%)		226 (49.3%)	110 (47.8%)	116 (50.9%)	
Male only	72 (15.7%)	44 (19.1%)	28 (12.3%)		56 (12.2%)	40 (17.4%)	16 (7.0%)		68 (14.9%)	42 (18.3%)	26 (11.4%)	
Female only	96 (21.0%)	32 (13.9%)	64 (28.1%)		86 (18.8%)	32 (13.9%)	54 (23.7%)		90 (19.7%)	34 (14.8%)	56 (24.6%)	
Both	86 (18.8%)	50 (21.7%)	36 (15.8%)		62 (13.5%)	34 (14.8%)	28 (12.3%)		68 (14.9%)	34 (14.8%)	34 (14.9%)	

* p<0.05, ** p<0.01; chi-square tests for each type of IPV were based on any report vs. never report by condition assignments

Note:

a. There are missing responses from 2 participants at the baseline assessments.

Variables Related to Sexual Risk:

Measures of risky sexual behaviors were self-reported as follows: (1) number of condomless vaginal and/or anal intercourse with all partners in the past 90 days; (2) number of sex partners in the past 90 day; (3) condom use intention; (4) condom use self-efficacy; and (5) number of times discussing with study partner how to prevent infection of HIV in the past 90 days. A higher intention or self-efficacy was indicated by a higher score on the scales [3].

Drug and Alcohol Use:

Alcohol and drug use included dichotomous variables indicating lifetime and past 90-day use of binge drinking (four or more drinks within five hours for males and four or more drinks within a six-hour period for females), heroin, prescription pain relievers, cocaine, crack, stimulants, tranquilizers, and other drugs.

Statistical Analysis

Chi-square ($\chi 2$) tests were used to test the differences between the couple's reports that one or both partners in a couple had a history of IPV versus neither partner reported a history of IPV between treatment conditions. $\chi 2$ tests or t-tests were also used to test the differences in the baseline characteristics based on if the couple reported a history of IPV and treatment conditions. Analyses focused on effectiveness—including moderation analyses—used an intent-to-treat approach. We employed Multiple Imputation procedures (MI) to impute values for missing data by using the information we observed or measured at prior assessments to predict values for missing variables. A total of 30 imputed datasets were generated. Next, we employed multilevel mixed-effects models to estimate the intervention effects moderated by whether the participants and/or their partners reported a history of perpetrating and/or experiencing any IPV. Hypothesis testing for the intervention effects was based on Incident Rate Ratios (IRR) from multilevel mixed-effects Poisson regression for the number of condomless sex acts, number of sex partners, and number of times discussing how to prevent HIV. The differences indicated by regression coefficients from mixed-effects linear regression were used for the scales of condom use intentions and condom use self-efficacy scales. To account for the unit of analysis, the individual participant nested in the dyad with repeated measures, the models included a random effect for the dyad to account for dependencies within the couple, and another random effect for repeated measures. The models also included three-way interactions for treatment condition, follow-up time, and the couple's reports of a history of

IPV. Finally, the models included covariate adjustments for the baseline measures of the outcome variables, gender, age, race/ethnicity, high school, single, homeless, not enough money for food, ever in prison, illicit drug use, and binge drinking. We then used the corresponding parameters associated with the treatment condition, time, history of IPV, and interaction terms to calculate the intervention effects for those who reported a history of IPV, those who did not, and the difference in intervention effects between these two groups. Statistical significance was assessed using the associated 95% Confidence Interval (CI) and $p < 0.05$ criterion for each estimate. MI procedures and statistical analyses were performed using Stata 14.

Results

Baseline IPV Rates by Study Condition

A total of 230 couples (N = 460 individuals) were randomized into either the PACT intervention condition (115 couples) or the HIV CTR control condition (115 couples). Table 1 describes the couple's reports of IPV history (perpetrating IPV, experiencing IPV, and combined perpetrating and experiencing IPV) for the total sample and stratified by condition assignment. Among the 230 couples, 33.2% (n = 152) of participants did not report experiencing or perpetrating any physical, injurious, or sexual IPV with their study partners, while 66.8% (n = 306) of participants reported any IPV (themselves, their partner, or both). Among these 306 participants, 20.1% of male participants (but not their female partners) reported IPV, 18.3% of female participants (but not their male partners) reported IPV, and 28.4% of participants and their partners both reported IPV. The χ^2 tests for comparing any partner versus neither partner reporting IPV by treatment conditions were not significant for combining perpetrating and experiencing IPV, but were significant for different types of perpetrating IPV ($\chi^2 = 3.87$, $p = 0.049$ for any perpetrating IPV; $\chi^2 = 6.78$, $p = 0.009$ for perpetrating physical IPV; $\chi^2 = 9.23$, $p = 0.002$ for perpetrating injurious IPV; and $\chi^2 = 7.36$, $p = 0.007$ for perpetrating sexual IPV) and experiencing physical IPV ($\chi^2 = 4.74$, $p = 0.030$).

Baseline Reports of Perpetrating and Experiencing IPV by Gender of Partner

The rates of reporting perpetration of any physical IPV were slightly higher among female partners only (17.5%) compared to male partners only (13.1%), with 8.7% of both female and male partners reporting perpetrating IPV. However, the reports of experiencing any physical IPV were similar among both partners, with 12.2% of male partners

only, 14.4% of female partners, and 13.1% of both partners reporting experiencing any physical IPV. The rate of reporting perpetrating injurious IPV was very low (4.8%), with 2.6% of male partners only and 2.2% of female partners only reporting perpetrating any injurious IPV. Rates of experiencing any injurious IPV were also low (2.6% of male partners only, 2.6% of female partners only, and 0% of both partners). The rate of perpetrating any sexual IPV was higher among male partners only (20.1%) compared to female partners only (8.7%), with 4.4% of both partners reporting perpetrating sexual IPV. However, 17.9% of male partners only reported experiencing sexual IPV compared to 13.1% of female partners only and 3.1% of both partners. Rates of reporting perpetration of any psychological IPV were slightly higher among female partners only (18.8%) compared to male partners only (12.2%) and both partners (13.5%). However, 19.7% of female partners only reported experiencing psychological IPV compared to 14.9% of male partners only and 14.9% of both partners.

Table 2 describes sociodemographic characteristics and biological assays of STI status at baseline by the couple's report of a history of IPV and intervention assignment. Among the participants assigned to the HIV CTR condition, the percentages of binge drinking (lifetime and in the past 90 days) and illicit drug use in the past 90 days were significantly higher for those who reported a history of IPV than those who did not report any IPV (52.6% vs. 31.6% for ever binge drinking ($\chi^2 = 9.05$, p = 0.003), 33.8% vs. 15.8% for binge drinking in the past 90 days ($\chi^2 = 8.19$, p = 0.004), and 62.3% vs. 46.1% for illicit drug use in the past 90 days ($\chi^2 = 5.50$, p = 0.019)). However, those who did not report any IPV scored significantly higher on scales of condom use intentions (12.4 vs. 11.1, t = 2.49, p = 0.014) and condom use self-efficacy (11.5 vs. 9.1; t = 2.32, p = 0.021) than those who reported a history of IPV. Among the participants assigned to the PACT condition, significant differences between the participants reporting IPV and no IPV were found by marital status (55.3% vs. 73.7% for single, 38.8% vs. 22.4% for married ($\chi^2 = 7.29$, p = 0.026)), ever arrested (82.2% vs. 70.7%; $\chi^2 = 3.97$, p = 0.046), HIV infection (4.6% vs. 11.8%; $\chi^2 = 4.07$, p = 0.044), and the number of sex partners in the past 90 days (1.9 vs. 1.3; t = 2.25, p = 0.025). In addition, compared to those who reported a history of IPV, those who did not report any IPV had greater average scores on the scales of condom use intentions (13.1 vs. 11.7, t = 2.96, p = 0.003) and condom use self-efficacy (12.2 vs. 10.1; t = 2.03, p = 0.043).

The results of multilevel mixed effects models are shown in Table 3. Among the participants and/or their partners who reported history of IPV, and compared to the CTR participants over the 12-month study period, PACT participants had 36% fewer acts of condomless vaginal and/or anal intercourse with all partners (IRR = 0.64, 95% CI = 0.41–0.98, p = 0.041) and 25% fewer sex partners (IRR = 0.75, 95% CI = 0.61–0.93, p = 0.008), higher scores for condom use intentions (b = 0.85, 95% CI = 0.18–1.53, p = 0.013) and condom use self-efficacy (b = 2.22, 95% CI = 0.88–3.56, p = 0.001), and 2.41 times more frequent discussion with study partner regarding prevention of HIV infection (IRR = 2.41, 95% CI = 1.18–4.93, p = 0.016). During follow-up among the participants and their partners who did not report a history of IPV, a statistically significant intervention effect was found for the number of condomless vaginal and/or anal intercourse acts with all partners (IRR = 0.53, 95% CI = 0.29–0.97, p = 0.038) and number of sex partners (IRR = 0.71, 95% CI = 0.52–0.96, p = 0.026).

No significant differences were found in intervention effect estimates on any of these outcomes between couples who reported a history of IPV and couples without such IPV.

Discussion

Our study addressed a significant gap in extant literature on couple-focused HIV prevention interventions for people who are involved in the criminal legal system. Most of the prior studies on this topic looked at IPV perpetration or victimization and HIV risk reduction, but not among both heterosexual couples. Moreover, most studies exclude participants based on histories of IPV rather than considering whether the presence of a history of partner violence shapes the effectiveness of the intervention. Our study addressed these gaps by including people with histories of IPV and examined the overlap between IPV and HIV risk reduction, as an important first step in addressing this limitation. The randomization design and the high rates of participation, attendance, and retention are key strengths of this study. Findings did not reveal a statistically significant difference in effectiveness of the intervention among those with IPV compared to those without. It is important to note that our measure is IPV lifetime but didn't also exclude on whether or not there was current IPV present. Findings from this study suggests that IPV does not moderate the effectiveness of PACT among couples with a history of IPV in reducing condomless sex and number of sexual partners, promoting condom use intentions, condom self-efficacy, and communication about HIV risks. Our research supports prior studies finding high prevalence rates of IPV in study samples from clinical trials of correctional populations. Some couples disclosed ongoing physical violence and sexual coercion unrelated to their participation in PACT and received referrals to IPV services and counseling. However, there were no serious adverse events of IPV reported by participants, detected by staff, or identified in review of audio recordings

Table 2 Descriptive Statistics of the Sample Reported at the Baseline Assessment by Condition Assignment and Couple Reports of the History of Physical, Injurious, and Sexual IPV (N = 460)

	HIV CTR (n = 230)			PACT (n = 230)		
	No IPV (n = 76)	IPV (n = 154)	t or χ^2 test	Non IPV (n = 76)	IPV (n = 152)	t or χ^2 test
Age[a]	37.5 (13.2)	37.8 (12.9)	t=-0.16 (p = 0.871)	32.2 (13.1)	32.6 (11.6)	t=-0.22 (p = 0.830)
Black/African American	58 (76.3%)	120 (77.9%)	χ^2 = 1.12 (p = 0.572)	56 (73.7%)	105 (69.1%)	χ^2 = 4.97 (p = 0.083)
Hispanic/Latino	12 (15.8%)	27 (17.5%)		18 (23.7%)	30 (19.7%)	
High school and above[b]	52 (68.4%)	92 (60.5%)	χ^2 = 1.36 (p = 0.244)	49 (65.3%)	98 (64.5%)	χ^2 = 0.02 (p = 0.899)
Single, never married[c]	50 (65.8%)	81 (52.6%)	χ^2 = 3.77 (p = 0.151)	**56* (73.7%)**	**84* (55.3%)**	**χ^2 = 7.29 (p = 0.026)**
Married/Common law marriage[c]	22 (29.0%)	59 (38.3%)		**17* (22.4%)**	**59* (38.8%)**	
Unemployed in the past 90 days[c]	55 (72.4%)	109 (70.8%)	χ^2 = 0.06 (p = 0.802)	61 (80.3%)	109 (71.7%)	χ^2 = 1.95 (p = 0.162)
Homeless in the past 90 days[c]	5 (6.6%)	13 (8.4%)	χ^2 = 0.24 (p = 0.621)	5 (6.6%)	33 (14.5%)	χ^2 = 3.02 (p = 0.082)
Not enough money for food in the past 90 days[c]	31 (40.8%)	64 (41.6%)	χ^2 = 0.01 (p = 0.911)	29 (38.2%)	66 (43.4%)	χ^2 = 0.58 (p = 0.447)
Ever arrested[b]	62 (81.6%)	122 (80.3%)	χ^2 = 0.06 (p = 0.812)	**53* (70.7%)**	**125* (82.2%)**	**χ^2 = 3.97 (p = 0.046)**
Ever in jail[b]	43 (56.6%)	101 (66.5%)	χ^2 = 2.12 (p = 0.145)	44 (58.7%)	95 (62.5%)	χ^2 = 0.31 (p = 0.577)
Ever in prison[c]	16 (21.1%)	43 (27.9%)	χ^2 = 1.26 (p = 0.262)	14 (18.4%)	41 (27.0%)	χ^2 = 2.02 (p = 0.155)
Binge drinking: lifetime[b]	**24** (31.6%)**	**80** (52.6%)**	**χ^2 = 9.05 (p = 0.003)**	34 (45.3%)	73 (48.0%)	χ^2 = 0.15 (p = 0.702)
Binge drinking: past 90 days[d]	**12** (15.8%)**	**52** (33.8%)**	**χ^2 = 8.19 (p = 0.004)**	22 (29.3%)	45 (29.6%)	χ^2 = 0.002 (p = 0.966)
Illicit drug use: lifetime[b]	69 (90.8%)	136 (89.5%)	χ^2 = 0.10 (p = 0.756)	64 (85.3%)	138 (90.8%)	χ^2 = 1.53 (p = 0.217)
Illicit drug use: past 90 days[d]	**35* (46.1%)**	**96* (62.3%)**	**χ^2 = 5.50 (p = 0.019)**	37 (49.3%)	95 (62.5%)	χ^2 = 3.57 (p = 0.059)
HIV positive[c]	4 (5.3%)	13 (8.4%)	χ^2 = 0.75 (p = 0.386)	**9* (11.8%)**	**7* (4.6%)**	**χ^2 = 4.07 (p = 0.044)**
Any STI[c]	8 (10.5%)	29 (18.8%)	χ^2 = 2.60 (p = 0.107)	14 (18.4%)	26 (17.1%)	χ^2 = 0.06 (p = 0.805)
# condomless vaginal and/or anal intercourse with all partners in the past 90 days[b]	26.0 (32.0)	32.0 (36.9)	t=-1.20 (p = 0.230)	23.6 (33.4)	31.5 (36.3)	t=-1.59 (p = 0.112)
# of sex partners in the past 90 days[e]	2.0 (5.8)	2.0 (2.0)	t = 0.14 (p = 0.890)	**1.3* (1.3)**	**1.9* (2.1)**	**t=-2.25 (p = 0.025)**
Condom Use Intentions[c]	**12.4* (3.3)**	**11.1* (3.7)**	**t = 2.49 (p = 0.014)**	**13.1** (2.7)**	**11.7** (3.6)**	**t = 2.96 (p = 0.003)**
Condom Use Self-Efficacy[c]	**11.5* (7.3)**	**9.1* (7.9)**	**t = 2.32 (p = 0.021)**	**12.2* (7.0)**	**10.1* (7.2)**	**t = 2.03 (p = 0.043)**
Number of times discussing with study partner how to prevent infection of HIV in the past 90 days[f]	8.6 (21.0)	10.2 (26.4)	t=-0.43 (p = 0.661)	9.1 (23.4)	7.2 (20.8)	t = 0.61 (p = 0.546)

* p < 0.05, ** p < 0.01; tests of difference between Non-IPV and IPV groups by t-test or chi-square test with each condition

Note:

a. There is 1 missing value.

b. There are 5 missing values.

c. There are 2 missing values.

d. There are 3 missing values.

e. There are 4 missing values.

f. There are 24 missing values.

Table 3 Multilevel Models of Intervention Effect Estimates for Primary and Secondary Outcomes at Each Follow-up and Over the Entire Follow-up Period by Couple Reports of the History of Any Physical, Injurious and Sexual IPV

		Entire follow-up	3-month	6-month	12-month
# condomless vaginal and/or anal intercourse with all partners in the past 90 days *(IRR)*	Non-IPV	**0.53*** **[0.29, 0.97]** **(p = 0.038)**	0.55 [0.30, 1.03] (p = 0.061)	**0.53*** **[0.29, 0.97]** **(p = 0.040)**	**0.48*** **[0.26, 0.89]** **(p = 0.020)**
	IPV	**0.64*** **[0.41, 0.98]** **(p = 0.041)**	0.69 [0.44, 1.06] (p = 0.091)	0.54 [0.27, 1.05] (p = 0.070)	0.50 [0.22, 1.15] (p = 0.104)
	Diff.	1.22 [0.58, 2.53] (p = 0.604)	1.24 [0.58, 2.64] (p = 0.575)	1.21 [0.58, 2.54] (p = 0.607)	1.16 [0.54, 2.49] (p = 0.700)
# of sex partners in the past 90 days *(IRR)*	Non-IPV	**0.71*** **[0.52, 0.96]** **(p = 0.026)**	**0.65*** **[0.44, 0.94]** **(p = 0.022)**	**0.70*** **[0.51, 0.95]** **(p = 0.023)**	0.81 [0.55, 1.18] (p = 0.273)
	IPV	**0.75**** **[0.61, 0.93]** **(p = 0.008)**	**0.72*** **[0.55, 0.93]** **(p = 0.013)**	**0.63*** **[0.41, 0.97]** **(p = 0.038)**	0.60 [0.31, 1.16] (p = 0.126)
	Diff.	1.06 [0.74, 1.53] (p = 0.741)	1.11 [0.72, 1.70] (p = 0.637)	1.07 [0.74, 1.54] (p = 0.716)	1.00 [0.62, 1.59] (p = 0.990)
Condom Use Intentions *(b)*	Non-IPV	0.41 [-0.50, 1.33] (p = 0.377)	0.80 [-0.33, 1.93] (p = 0.163)	0.51 [-0.42, 1.44] (p = 0.285)	-0.07 **[**-1.27, 1.13] (p = 0.909)
	IPV	**0.85*** **[0.18, 1.53]** **(p = 0.013)**	0.66 [-0.17, 1.48] (p = 0.118)	1.29 [-0.59, 3.17] (p = 0.178)	2.27 [-1.38, 5.93] (p = 0.222)
	Diff.	0.44 [-0.67, 1.55] (p = 0.438)	-0.14 [-1.51, 1.22] (p = 0.838)	0.29 [-0.84, 1.43] (p = 0.611)	1.17 [-0.28, 2.61] (p = 0.113)
Condom Use Self-Efficacy *(b)*	Non-IPV	0.11 [-1.71, 1.94] (p = 0.903)	-0.16 [-2.37, 2.05] (p = 0.889)	0.05 [-1.81, 1.90] (p = 0.962)	0.45 [-1.88, 2.78] (p = 0.704)
	IPV	**2.22**** **[0.88, 3.56]** **(p = 0.001)**	**2.10*** **[0.47, 3.73]** **(p = 0.012)**	0.27 [-1.50, 2.03] (p = 0.768)	1.11 [-3.02, 5.24] (p = 0.598)
	Diff.	2.11 [-0.12, 4.34] (p = 0.064)	2.26 [-0.48, 4.99] (p = 0.106)	2.15 [-0.13, 4.43] (p = 0.065)	1.93 [-0.90, 4.75] (p = 0.181)
Number of times discussing with study partner how to prevent infection of HIV in the past 90 days *(IRR)*	Non-IPV	1.20 [0.49, 2.92] (p = 0.695)	1.23 [0.50, 3.00] (p = 0.656)	1.20 [0.49, 2.92] (p = 0.692)	1.14 [0.46, 2.86] (p = 0.776)
	IPV	**2.41*** **[1.18, 4.93]** **(p = 0.016)**	**2.98**** **[1.44, 6.15]** **(p = 0.003)**	1.04 [0.41, 2.63] (p = 0.932)	0.75 [0.27, 2.08] (p = 0.583)
	Diff.	2.01 [0.66, 6.13] (p = 0.218)	2.43 [0.79, 7.50] (p = 0.122)	2.10 [0.69, 6.39] (p = 0.190)	1.57 [0.51, 4.91] (p = 0.433)

* $p < 0.05$; ** $p < 0.01$

Note:

Multilevel models included random effects for couple and repeated measures, and covariate adjustments for baseline measures of the outcomes, gender, age, black, high school, single, homeless, not enough money for food, ever in prison, illicit drug use and binge drinking.

by clinical supervisors. These findings are reassuring insofar as safety concerns have thus far been a substantial barrier to implementing couple-level interventions in the field. Considering the dearth of prior literature on this topic, our findings provide a compelling justification for future research delving deeper into the role of IPV in shaping the effectiveness of couples-focused HIV prevention clinical trials.

Limitations

Despite the gaps addressed by our study, several limitations are worth noting. A null result should not be overinterpreted as rigorous evidence for no [moderation] effect. The analysis was stratified by study arm, but no analysis was done examining gender differences with moderation analysis of IPV; the typology of couple-level IPV for differences among male only, female only, and both; or if male partners perpetrated such IPV against female partners, female partners against male partners, or both. Understanding such

differences could have provided additional insight into whether the intervention effects differed by type of IPV and whether male partners only, female partners only, or both partners reported experiencing and perpetrating IPV. In addition, no significant differences were found between treatment conditions on the key moderator variable of perpetrating and/or experiencing any physical, injurious, or sexual IPV. There were significant differences between conditions in perpetrating any physical, injurious, and sexual IPV. PACT participants reported higher rates of perpetrating physical, injurious, and sexual IPV than TAU participants [3]. Future research with larger sample sizes is needed to examine whether such differences in perpetrating occurred by type and severity of IPV and whether IPV was mutual (both partners reported experiencing and/or perpetrating IPV) or reported only by male or female partners. This research could inform more refined guidelines and suggest the IPV subgroups most likely to benefit from this intervention.

The sample was limited to men in community supervision who use drugs and their female partners in New York City. Additionally, the participants were predominantly Black and Latinx, which may limit generalizability to other large cities with similar racial and ethnic compositions. In future studies, it is recommended to have a more diverse sample of drug-involved men under community supervision and their main sexual partners, paying special attention to certain less-studied groups of couples such as Latinx couples. Unfortunately, we did not collect data regarding violence from other partners, sexual orientation, or same-sex sexual behavior for this study. The lack of data collected for same-sex sexual behavior is a significant limitation as it is well documented in the literature that some heterosexual men who were formerly incarcerated engage in same-sex relationships, which is a considerable risk for HIV transmission [9]. Thus, we do not know the effects of same-sex relationships and sexual orientation identity on this study's outcomes. Future research should include sexual orientation and same-sex relationship status or identity as a control variable. Finally, although there were no differences in baseline socio-demographics and outcomes between PACT participants and control participants except for age, as reported elsewhere [3], there were some differences between treatment conditions by IPV status. Further research should examine potential mediators (e.g., communication and negotiation skills) of the intervention on HIV risk and IPV outcomes and do so among different IPV subgroups. It should also include qualitative techniques, which would enrich the data interpretation in identifying core intervention components.

Implications for Future Couples-Focused HIV Prevention Research with People with Criminal Legal System Involvement

Several avenues of future research arise from this study. First, it is well documented that Black, Latinx, and other minority and marginalized populations are overrepresented in the criminal legal system and populations under community supervision [36]. Black and Latinx people are also disproportionately burdened by both IPV and HIV making structural racism an important social determinant of health for these dual epidemics [37–40] due to racialized drug policies and policing [39]. Our study did not examine how the moderating effects IPV on HIV prevention outcomes may differ across subgroups by race and gender. Therefore, future research should consider tailoring this intervention to different ethnic minority subgroups as well as measuring specific issues that may be disproportionately experienced by Black and Hispanic couples including police violence, sexual misconduct and discrimination [4, 13, 41–46].

Second, there is myriad negative health and mental health consequences of IPV and high rates of IPV among couples in the criminal legal system. Future research must investigate how IPV shapes the effectiveness of other critical interventions within criminal legal settings including those for mental health and substance misuse. Several syndemic disparities—including elevated HIV/STI risk, substance abuse, including overdose, trauma, and PTSD—will continue to increase unless IPV victimization among substance-using populations receiving community supervision is addressed [13, 15, 25]. Syndemics of HIV and other health problems remain a significantly understudied topic in criminal legal system settings. Future research must investigate if including a focus on IPV in couples-focused interventions could be helpful in attenuating the presence of syndemic health problems among people who are involved in the criminal legal system.

Third, greater research is needed that examines how cumulative exposures to other forms of violence throughout the developmental life-course moderates the impact of our clinical trial on key HIV prevention outcomes. People who are exposed to IPV are at greater risk of having experienced other forms of trauma early on in the developmental life-course including early childhood sexual abuse and neglect [9, 23]. Cumulative trauma may increase vulnerability to HIV and reduce engagement and retention in clinical trials. Future research must investigate (1) how IPV intersects with other forms of trauma and determine if there are cumulative impacts of trauma across multiple types of violence on the effectiveness of Project PACT; (2) the role of a greater number of contextual factors, for example, targeting sex-specific factors, frequency of violent acts, and HIV risk reduction on retention and engagement in moderating the

effects of HIV prevention clinical trials; and (3) the relationship between physical, sexual, and psychological IPV and the different types of risk reduction outcomes reported.

Fourth, people with IPV may be exposed to systemic forms of trauma from the criminal legal system such as sexual abuse by police and corrections officers, and other forms of physical violence at greater rates that discourage them from accessing services through probation settings. This could result in fewer people with histories of IPV accessing services and greater rates of unreported IPV due to fear and lack of trust. We did not measure trust in the medical system which could be an important mediating factor shaping the effectiveness of HIV clinical trials. Our future research will test whether or not people who are exposed to IPV may have lower trust in the medical system thereby discouraging them from disclosing their IPV and receiving services.

Fifth, Greater screening and assessment instruments are needed within community supervision settings to identify people who are receiving services with a history of IPV who could potentially benefit from services that redress syndemics of HIV and other co-occurring conditions among people who are involved in the criminal legal system. The recent spike in IPV rates nationwide since the start of the COVID-19 pandemic further highlights the need for such IPV screening and interventions. Underreporting of IPV is a major concern in couples-focused interventions and refining screening and assessment techniques could enhance the detection of underlying IPV in clinical trials research. Community supervision staff need to be trained to identify and address these issues and have strategies for referring out to HIV and IPV services. Sixth, future research must include PrEP in HIV prevention clinical trials for couples in the criminal legal system given their disproportionately high rates of IPV and HIV. Although there has been some attention paid to the use of PrEP for preventing HIV among women experiencing IPV [47–51], couple-focused research lags.

Seventh, exploring different modalities such as electronic tools for IPV and HIV risk screening should become an integral part of legal system involved programs as it could potentially improve health outcomes among this population [52]. Additionally, in light of the pandemic, telehealth has been expanded, including in community supervision settings, which may afford an opportunity to build off of this and additional research needs to be done to better understand and explore the barriers and challenges to using technology and telehealth among this group [52]. Now more than ever, the need is greatest to integrate technology into prevention interventions [17, 52]; this innovation will be instrumental in reducing the disparities in both HIV and IPV among vulnerable populations [13, 53, 54]. Integrated tools should also include education on the increased risk of HIV and STI infection and how couples can stay safe, including PrEP education and adherence.

Conclusion

Elevated rates of HIV, IPV and substance misuse among men in criminal legal system and their female partners underscore the urgent public health need for couple-based HIV interventions that are effective and safe for couples where IPV is present [18]. Future research studies are needed that investigate facilitators and barriers of retention in care for black and Latinx couples with histories of IPV from within community supervision settings to enhance retention among a population that is disproportionately marginalized from access to critical HIV prevention resources. The high rates of IPV and HIV risks in our sample support the applicability of our intervention to similar couple-oriented approaches to reduce HIV risks among partners involved in the criminal legal system with a high prevalence of IPV. Despite the challenges of working with couples experiencing IPV, our findings suggest that such couples may benefit from couples-based HIV interventions. Our study findings provide support for targeting both men and women impacted by IPV as a potential group for HIV risk reduction among couples involved in the criminal legal system. Our study has implications for the types of HIV interventions that may be useful for addressing the needs of the large number of couples in the criminal legal system who are at risk for co-occurring HIV risks, substance misuse and IPV. There remains an urgent need for future intervention research conducted in community supervision settings among couples that focuses on IPV perpetration and victimization, as well as physical, sexual, and psychological risk.

Data Availability Not applicable.

Code Availability Not applicable.

Declarations

Conflict of interest The authors declare that they have no competing interests.

Ethics approval and consent to participate All procedures performed were in accordance with the ethical standards of the Columbia University institutional review board. The procedures used in this study adhere to the tenets of the Declaration of Helsinki. Informed consent was obtained from all individual participants included in the study.

Consent for publication Not applicable.

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