A peer-education intervention to reduce injection risk behaviors for HIV and hepatitis C virus infection in young injection drug users

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Objectives: To evaluate whether a behavioral intervention, which taught peer education skills, could reduce injection and sexual risk behaviors associated with primary HIV and hepatitis C virus infection (HCV) among young injection drug users (IDU).

Design: We conducted a randomized controlled trial involving HIV and HCV antibody-negative IDU, aged 15–30 years, recruited in five United States cities. A six-session, small-group, cognitive behavioral, skills-building intervention in which participants were taught peer education skills ($n = 431$) was compared with a time-equivalent attention control ($n = 423$). Baseline visits included interviews for sociodemographic, psychosocial, and behavioral factors during the previous 3 months; HIV and HCV antibody testing; and pre/posttest counselling. Procedures were repeated 3 and 6 months postintervention.

Results: The intervention produced a 29% greater decline in overall injection risk 6 months postintervention relative to the control [proportional odds ratio 0.71; 95% confidence limit (CL) 0.52, 0.97], and a 76% decrease compared with baseline. Decreases were also observed for sexual risk behaviors, but they did not differ by trial arm. Overall HCV infection incidence (18.4/100 person-years) did not differ significantly across trial arms (relative risk 1.15; 95% CL 0.72, 1.82). No HIV seroconversions were observed.

Conclusion: Interventions providing information, enhancing risk-reduction skills, and motivating behavior change through peer education training can reduce injection risk behaviors, although risk elimination might be necessary to prevent HCV transmission.

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Introduction

Injection drug use remains the leading risk for HIV infection in many countries worldwide [1]. The prevalence of hepatitis C virus (HCV) infection among injection drug users (IDU) ranges from 30% to more than 90% with an incidence between 10 and 75/100 person-years [2–8]. These infections remain an enormous public health challenge as each involves a chronic carrier state facilitating ongoing transmission and costly medical consequences, including AIDS, cirrhosis, and hepatocellular carcinoma. Lacking vaccines to prevent infection, primary prevention relies on reducing the risk of exposure. Beyond syringe sharing, interventions are needed to prevent the sharing of other drug paraphernalia [9,10], drug preparations [11–13] and risky sexual behaviors among IDU [14–17].

Recently initiated IDU have higher HIV and HCV seroincidence than IDU with longer duration of use [18–21]. A study of 18–30-year-old IDU in six United States cities showed that sexual [22] and injection [10,23] risk behaviors were highly prevalent among young IDU, underscoring the need to structure and target interventions for recently initiated, typically younger IDU. Although some interventions not specifically focusing on younger IDU produced small reductions in risky injection behaviors [24–27], they were less effective at reducing sexual risk behaviors, particularly among steady sex partners [24,28,29], which may be more difficult to change [30–32].

Few primary HIV prevention interventions for IDU have been evaluated through randomized controlled trials [33], and none have directly addressed HCV infection. Although behavior change interventions based on cognitive–behavioral skills-building [34] and peer-based interventions [35] have been evaluated, those studies included non-IDU or IDU who were not recent initiates. Whereas modest effects were observed in cognitive–behavioral interventions among younger individuals and IDU [36–39], the extent to which an intervention combining cognitive–behavioral theory and peer education can more effectively reduce risk among young IDU has not been explored. We evaluated the efficacy of an intervention incorporating cognitive–behavioral skills-building into a programme designed to teach IDU how to provide peer education about sexual and injection risk reduction to decrease their own HIV and HCV infection risk.

Methods

Participants

Between May 2002 and January 2004, IDU were recruited through street outreach, advertising, and coupon-based participant referrals in Baltimore, Chicago, Los Angeles, New York, and Seattle. Eligible participants had injected illicit drugs in the past 6 months, resided in the recruitment city with no plans to move within 12 months, spoke English, were aged 15–30 years, were willing to undergo HIV and HCV antibody testing, and provided written informed consent. Trial-eligible participants had to test HIV and HCV antibody-negative at baseline. Further details are provided elsewhere [40].

Study design

The study, known to participants as 'DUIT', was a randomized controlled trial (Fig. 1). Pretest counselling was provided at baseline. Test results and face-to-face posttest counselling were given approximately 2 weeks later, before intervention trial enrollment. Counselling was based on Centers for Disease Control and Prevention (CDC) guidelines [41] and included comprehensive HIV and viral hepatitis risk-reduction information. When indicated, participants were referred for medical, drug treatment, and social services. Participants testing antibody negative for HIV and HCV at baseline were enrolled in the trial upon return for a subsequent visit during which a cohort of approximately 10–30 eligible participants was randomly assigned to trial arms. Sites varied by the number of cohorts (range 12–23). Study outcomes were assessed at 3 and 6-month postintervention follow-up visits. Participants were remunerated for time and travel after each visit per local norms. Institutional review boards at CDC and all collaborating institutions approved the study protocol.

Trial arm assignment was conducted by one staff member at each site, who was not an intervention facilitator, using a computer program provided by the central data manager, which individually randomly assigned participants immediately before the intervention began. Randomization stratified participants by sex and age (< 18 and ≥ 18 years) with a block size of six to achieve similar participant ratios across arms. Mid-enrollment, group assignment was amended to stop the loss of participants who became frustrated by rescheduling random assignments as a result of low turnout. Thereafter, when the number of participants arriving for random selection was between five and nine the whole cohort was randomly assigned to one trial arm by drawing group assignments from sealed envelopes.

Intervention methods

Theories guiding the DUIT peer education intervention (PEI) included social learning theory [42] and the information, motivation, and behavioral skills model [43]. As a framework for education and skills-building activities, the intervention centered on teaching participants how to educate peers about HIV and HCV risk reduction. By encouraging participants to adopt this new prosocial role, we intended to motivate them to change their own behaviors. The PEI consisted of six 2-h sessions over a 3-week period. Sessions were conducted by two facilitators, at least one of whom was female. Session 1 described HIV and HCV transmission through sex and injection drug use, informed participants about disease

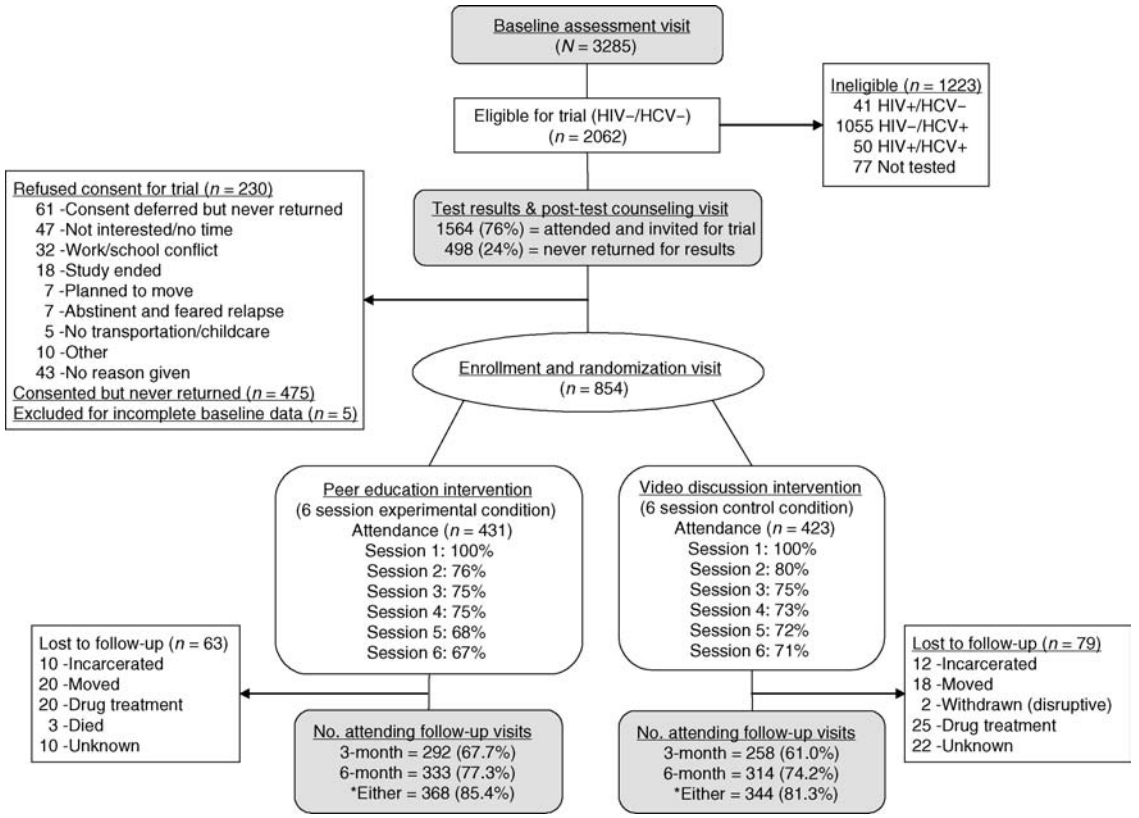

Fig. 1. Flow diagram of the 3rd Collaborative Drug Users Study/Drug Users Intervention Trial study visits and participation rates, 2002–2004. HCV, Hepatitis C virus. *Included in analysis.

prevalence in their communities, and described the vital role peer educators play in preventing further disease spread. Sessions 2 and 3 provided peer education about safer injection and sexual practices, respectively, with activities designed to increase negotiation skills with sex and injection partners. Session 4 added skills-building activities and prepared participants to demonstrate peer education in settings observable to intervention facilitators (e.g. an information table on the street or near a syringe exchange programme). During session 5, small teams of up to five participants conducted 90-min peer education sessions. Participants debriefed afterwards with the facilitator, who reinforced positive experiences and minimized potentially negative reactions. Session 6 consisted of a large group debriefing, goal-setting to encourage continued risk reduction, and a graduation ceremony. Intervention details and development methods are described elsewhere [44].

Participants randomly assigned to the attention–control arm received a video discussion intervention (VDI) comprising equivalent hours and sessions as the PEI. VDI participants watched hour-long films addressing social (e.g. gun violence, gangs, prejudice) and health (e.g. cardiopulmonary resuscitation training, alcoholism, injury prevention) issues followed by facilitated discussion using scripted questions. Risk-reduction topics were diverted by offering the same education pamphlets given to PEI participants.

Data collection

At baseline and 3 and 6-month follow-up visits, participants completed behavioral risk interviews using audio computer-assisted self-interviewing (ACASI). Interviews were administered before pretest counselling and venipuncture to minimize reporting bias.

Outcome measures

Multiple outcome measures were assessed to determine whether the intervention had an effect on decreasing several sexual and injection risk behaviors. Methods employed to enhance the validity of participants' self-reported behaviors included: (i) using ACASI to minimize interviewer bias and socially desirable responding [45–47]; (ii) excluding intervention facilitators from follow-up assessment activities to avoid a booster effect; (iii) using study ID numbers instead of names during data collection; and (iv) using calendars and a brief recall period (3 months) to maximize recall. HCV antibody seroconversion during follow-up provided a biological outcome measure.

Self-reported injection behaviors

Key injection risk indicators included the proportion of all injections during the previous 3 months that involved: (i) injecting with a syringe used previously by another IDU; (ii) using a new sterile syringe to divide drugs with another IDU when drugs were split; (iii) sharing cookers; (iv) sharing cotton filters; and (v) sharing rinse water.

Questions regarding these risk indicators included seven-item response categories (1, 'never'; 2, 'rarely'; 3, 'less than half the time'; 4, 'about half the time'; 5, 'more than half the time'; 6, 'almost always'; 7, 'always'). The drug-splitting variable had reverse-coded response categories making higher values equate to greater risk. We also assessed the number of injection partners in the past 3 months, and the proportion with whom participants shared injection equipment with on a seven-item scale (1, 'none'; 2, 'almost none'; 3, 'less than half'; 4, 'about half'; 5, 'more than half'; 6, 'almost all'; 7, 'all'). A composite injection risk variable was created by summing the six proportion variables and dividing by six to produce a single outcome measure with values ranging from one to seven (Cronbach's alpha 0.83).

Self-reported sexual behaviors

Participants were asked for the number of vaginal and anal sex acts, with and without condoms, stratified by partner type (main steady, other steady, and casual or sex trade partners). By definition, participants could have only one 'main steady' sex partner, but multiple 'other steady' sex partners. Six sexual risk outcomes were computed enumerating unprotected vaginal or anal intercourse acts with a main partner, other steady partners, or casual/sex trade partners. Summing these variables provided the total number of unprotected sex acts with all partners during the past 3 months.

Serological testing

Incident HCV infection was defined as a positive laboratory test result for HCV antibodies (anti-HCV) on both enzyme immunoassay (ORTHO HCV version 3.0 enzyme-linked immunosorbent assay; Ortho-Clinical Diagnostics, Raritan, New Jersey, USA) and recombinant immunoblot assays (recombinant immunoblot assay; Chiron Corporation, Emeryville, California, USA) from blood samples collected at 3 or 6-month follow-up assessments. HIV antibody testing employed standard enzyme-linked immunosorbent assay and Western blot procedures.

Statistical analyses

We conservatively calculated sample size by basing it on the behaviors we expected to be least prevalent at baseline from previous studies [22,48]. Estimating 20% baseline prevalence, 20% attrition over the 6-month follow-up period and setting the type I error rate at 0.05 for a two-tailed test with 80% power, we needed 725 participants per arm to detect at least a 30% decrease in each risk behavior among PEI participants compared with VDI participants.

All analyses were performed in a blinded fashion. Between-group differences at baseline were determined using chi-square tests for nominal variables or Wilcoxon rank sum tests for count variables. A priori hypotheses guided intention-to-treat analyses [49]. To account for variation between participants in time to follow-up, 6-month intervention effects were assessed testing whether differential rates of linear change occurred over the entire study period using a group-by-time interaction.

Injection outcomes were modelled by using cumulative logit models for repeated ordinal data with the inclusion of a random intercept to account for baseline participant differences [50,51]. Multivariate models were fit adjusting for city, race, sex, cohort size, age, and men who have sex with-men (MSM) or women who have sex with women sex when these variables were associated with the outcome measures. Proportional odds ratios and 95% confidence limits (CL) were estimated using SAS Proc NLMIXED [52] to determine intervention effects on 6-month changes in risk behavior. A score chi-square test was used to evaluate the proportional odds assumption that the intervention effect was constant for all seven response categories in each outcome measure.

The composite injection variable was created posthoc from the six injection variables because the intervention's effect was in the same direction across variables. Given that missing data on individual injection variables could have affected the composite variable, we modelled each individual injection variable separately and estimated the overall injection risk as the weighted average of the odds ratios from separate models for each injection outcome. Weights were the inverse variances for the intervention effect from each model. To compute variances and 95% CL, correlations between these non-independent measures for each behavior were calculated from participants' average monthly behavior change score for each outcome.

Unprotected sexual behavior outcomes were modelled using a negative binomial fit of repeated count data that included a random intercept to account for within-subject correlation [51,52]. Zero-inflated negative binomial models (STATA software, version 8; STATA Corp., College Station, Texas, USA) with robust variance estimates and two components, a logit component of the zero probability and a negative binomial component of the frequency count, were implemented to capture excessive zero responses and extreme values [53]. Wald and likelihood-ratio tests for evaluating fit and the Vuong test for assessment of zero inflation were computed [54]. A summary measure for the six sexual outcome models was not applicable because heterogeneous associations with the outcomes by arm were observed. All model results are reported in terms of 6-month change.

Results

A total of 3285 IDU completed the baseline assessment. Of 2062 participants who tested HIV and HCV antibody negative and were eligible for the trial, 854 were enrolled (Fig. 1). Enrolled participants were slightly older than non-enrolled eligible participants (Table 1). In addition,

Table 1. Characteristics of 15–30-year-old injection drug users, 3rd Collaborative Injection Drug Users Study/Drug Users Intervention Trial, 2002–2004.

Variable		Completed baseline ($n=3285$)	Eligible for trial (HIV and HCV antibody negative)		
			Not enrolled ($n=1172$)	Enrolled ($n=854$)	Total ($n=2026$)
Age in years	Mean (IQR)	23.8 (21–27)	22.9 (20–25)	23.8 (21–27)*	23.8 (21–27)
Minors	15–17 years	2.2%	1.8%	2.7%	3.0%
Sex	Male	68.9%	67.9%	66.5%	67.3%
	Female	30.4%	31.4%	32.8%	32.0%
	Transgender	0.8%	0.7%	0.7%	0.7%
Race/ethnicity	NH black	7.7%	9.1%	8.4%	8.8%
	NH white	64.0%	65.3%	63.3%	64.5%
	Hispanic	16.8%	13.4%	17.1%	15.0%
	Other/mixed	11.5%	12.2%	11.2%	11.8%
Homeless in the past 6 months		49.6%	50.8%	43.2%*	47.6%
HIV antibody positive		2.9%	–	–	–
HCV antibody positive		34.4%	–	–	–

HCV, Hepatitis C virus; NH, non-Hispanic; IQR, interquartile range.
*$P<0.001$ comparing enrolled with non-enrolled participants.

enrolled participants were less likely to have been homeless during the 6 months before baseline (43.2% versus 50.8%; $P<0.001$), but were similar on all other sociodemographic and outcome variables (data not shown). Of the participants enrolled, 431 were randomly assigned to the PEI and 423 to the VDI arm. The only significant baseline difference between these arms was in the percentage of MSM (Table 2). No adverse events occurred in either arm.

Overall, 712 (83%) participants returned for at least one follow-up assessment (Fig. 1) and were included in the analysis; 485 (57%) returned for both. Slightly more PEI than VDI participants returned for the 3-month assessment (68 versus 61%; $P=0.04$), but return rates were similar at 6 months (77 versus 74%; $P=0.30$).

Effect of the peer education intervention

All six injection outcome variables and the composite index measure decreased significantly at follow-up compared with baseline among PEI participants, as did all but one measure in the VDI arm (Table 3). Declines in the PEI arm compared with the VDI arm ranged from 26 to 39% across measures, although none reached statistical significance individually. The intervention effect was, however, statistically significant for the composite measure [unweighted average of participants' responses to the six outcome measures; proportional odds ratio (POR) 0.64; 95% CL 0.44, 0.94]. Furthermore, a weighted average from models of the six individual outcome measures demonstrated a 29% greater decline in overall risk among PEI compared with VDI participants (POR 0.71; 95% CL 0.52, 0.97).

Participants within each trial arm reported fewer unprotected sex acts in all categories at follow-up compared with baseline, although not all outcomes were statistically significant (Table 4). A statistically significant difference between trial arms was observed for only one sexual outcome measure. After adjusting for potential confounders, unprotected 'anal sex with casual/sex trade partners' decreased more among VDI participants compared with PEI participants. Given a high proportion of zero responses, particularly for the frequency of unprotected anal sex outcomes, we reanalysed the data using zero-inflated negative binomial mixture models. We observed a significantly greater reduction in the frequency component of 'anal sex with a main partner' among PEI versus VDI participants (risk ratio 0.54; 95% CL 0.33, 0.87). In addition, there was no longer a significant difference in 'anal sex with casual/sex trade partners' by trial arm (data not shown).

The overall incidence of HCV infection was 18.1/100 person-years (95% CL 14.4, 23.0). Using Poisson regression to control for site, race, sex, age, and cohort size, we found no difference in HCV incidence rates between PEI and VDI participants (relative risk 1.15; 95% CL 0.72, 1.82). No participants seroconverted to HIV positive in either trial arm during the 427 person-years of follow-up.

Discussion

Our intervention, which provided information and skills for reducing sexual and injection risk associated with HIV and HCV infection and encouraged young adult IDU to adopt prosocial roles as peer educators, produced a 29% greater reduction across six injection risk behaviors compared with the attention–control participants. Previous intervention trials among HIV-positive IDU [55] have demonstrated decreases in unprotected sex and sexually transmitted diseases, but not needle sharing as shown here.

This is the first intervention tested in a randomized controlled trial specifically focused on young HIV and

Table 2. Results of random assignment to trial arm among 15–30-year-old injection drug users, 3rd Collaborative Injection Drug Users Study/ Drug Users Intervention Trial, 2002–2004.

Variable[a]	Peer education intervention ($n = 431$)	Video discussion intervention ($n = 423$)
Participant characteristics		
Years of age at baseline visit	23.8 (3.5)	23.8 (3.7)
Male sex, *N* (%)[b]	285 (66.1)	282 (66.7)
Did not complete 12th grade, *N* (%)	147 (34.2)	147 (34.8)
Most income from full or part-time job in past 6 months, *N* (%)	188 (43.8)	182 (43.3)
Mostly lived away from parents in past 6 months, *N* (%)	269 (62.7)	260 (61.8)
Considered self homeless in past 6 months, *N* (%)	187 (43.4)	180 (42.8)
Ever traded sex for money or drugs, *N* (%)	109 (25.5)	115 (27.6)
Ever incarcerated, *N* (%)	298 (69.1)	288 (68.1)
In drug treatment now (excl. support groups), *N* (%)	41 (11.1)	50 (13.4)
Age of first injection in years	19.5 (3.8)	19.3 (4.0)
Duration of injection drug use in years	4.2 (3.4)	4.4 (3.5)
Injection behaviors in past 3 months		
Mostly injected heroin not mixed with other drugs, *N* (%)	323 (77.6)	316 (77.5)
Total no. of injections	202 (186)	202 (231)
Receptively shared syringes[c]	2.1 (1.5)	2.1 (1.6)
Cleaned syringe with bleach before receptively shared syringes[c]	3.8 (2.4)	3.5 (2.4)
Used new syringes to divide drugs[c]	2.8 (1.6)	2.9 (1.6)
Split drugs while in solution (e.g. 'backload')[c]	2.1 (1.8)	2.1 (1.7)
Split drugs with a syringe used by another IDU[c]	3.4 (2.0)	3.2 (2.1)
Shared cooker[c]	3.1 (2.2)	3.1 (2.1)
Shared cotton[c]	2.7 (2.1)	2.6 (2.0)
Shared rinse water[c]	2.8 (2.1)	2.7 (2.1)
Shared any injection equipment with other IDU[d]	2.9 (2.2)	2.8 (2.1)
Sexual behaviors in past 3 months		
Total no. of sex partners	6.5 (42.2)	4.3 (10.8)
Man who had male sex partners, *N* (%)	15 (5.5)	30 (10.8)[e]
Woman who had female sex partners, *N* (%)	26 (18.3)	26 (18.8)
No. of unprotected vaginal sex acts		
With main steady partner	29.0 (62.1)	29.7 (69.9)
With non-main steady partner	1.6 (6.7)	1.3 (7.2)
With casual/sex trade partner	5.1 (22.9)	6.7 (53.0)
No. of unprotected anal sex acts		
With main steady partner	2.7 (11.5)	2.4 (12.8)
With non-main steady partner	0.4 (3.1)	0.6 (7.0)
With casual/sex trade partner	0.8 (5.1)	3.3 (50.3)

IDU, Injection drug user.
[a]Data are expressed as mean (SD) unless otherwise noted.
[b]Male sex includes three participants in each arm who reported being transgendered male to female.
[c]Response categories: 1, 'never'; 2, 'rarely'; 3, 'less than half the time'; 4, 'about half the time'; 5, 'more than half the time'; 6, 'almost always'; 7, 'always'; 'Cleaned syringe with bleach' and 'Used new syringes to divide drugs' were reverse-coded to make higher values represent greater risk.
[d]Response categories for partners shared injection equipment with: 1, 'none'; 2, 'almost none'; 3, 'less than half'; 4, 'about half'; 5, 'more than half'; 6, 'almost all'; 7, 'all'.
[e]Chi-square $P = 0.02$ for the difference between trial arms.

HCV-uninfected IDU that stressed risk reduction for both infections. As HCV is primarily spread through parenteral routes among IDU, interventions that decrease unhygienic injection practices could reduce its spread; and given that HCV-associated liver disease is often silent for decades, interventions that merely delay infection among young IDU could significantly impact public health. Similarly, parenteral HIV transmission would also be decreased. Despite self-reported injection risk reduction in the PEI group, HCV infection incidence did not differ across trial arms, suggesting that exposure to infected blood must be virtually eliminated, rather than simply reduced, to prevent HCV infection. In studies of needlestick injuries sustained by healthcare workers, the proportion of infections after percutaneous injury was 10-fold higher for HCV than HIV [56]. This could also explain why HCV but not HIV transmission readily occurs among IDU who share injection paraphernalia other than syringes.

The effect of the PEI on condom use was less clear. As with injection risk behaviors, the frequency of all sexual risk behaviors declined in both trial arms over time. The only significant difference across arms was a greater decrease in unprotected anal sex with casual/sex trade partners among VDI versus PEI participants. Of note is the fact that this was the least commonly reported sexual risk behavior and less than 8% of men reported being MSM, explaining some of the instability in this estimate. Upon reanalysis using a mixture model, the difference in anal sex with casual/sex trade partners became non-significant. Instead, results from the frequency component indicated that unprotected anal

Table 3. Comparison of 6-month changes in injection risk behaviors among 15–30-year-old injection drug users participating in a peer education intervention or video discussion intervention, 3rd Collaborative Injection Drug Users Study/Drug Users Intervention Trial, 2002–2004.

	PEI arm 6-month change POR (95% CL)	VDI arm 6-month change POR (95% CL)	Intervention effect[a] (change in PEI/VDI) POR (95% CL)	*P*
Composite index of all six items[b]	0.18 (0.14, 0.25)	0.29 (0.22, 0.39)	0.64 (0.44, 0.94)	0.024
Summary measure of all six models[b]	0.24 (0.19, 0.31)	0.37 (0.29, 0.46)	0.71 (0.52, 0.97)	0.029
Individual items				
Proportion of injections in which[c]				
Injected with used syringe	0.29 (0.22, 0.40)	0.42 (0.31, 0.57)	0.71 (0.47, 1.07)	0.105
Used new syringe to divide drugs[d]	0.49 (0.29, 0.83)	0.88 (0.54, 1.42)	0.61 (0.31, 1.19)	0.145
Shared cooker	0.22 (0.16, 0.29)	0.35 (0.27, 0.46)	0.73 (0.50, 1.06)	0.099
Shared cotton	0.24 (0.17, 0.33)	0.38 (0.28, 0.50)	0.69 (0.46, 1.04)	0.074
Shared rinse water	0.27 (0.20, 0.36)	0.35 (0.27, 0.47)	0.74 (0.51, 1.09)	0.133
Proportion of partners with whom you shared injection paraphernalia[e]	0.13 (0.09, 0.18)	0.22 (0.16, 0.31)	0.69 (0.44, 1.10)	0.117

CL, Confidence limit; PEI, peer education intervention; POR, proportional odds ratio; VDI, video discussion intervention.
[a]Estimates result from random intercept proportional odds models (cumulative logit). The intervention effect is estimated with a time trend by study arm, two-way interaction term in the model. Significant covariates potentially included in models were city, race, sex, cohort size, and age.
[b]The composite index was calculated by adding the response values from six outcome measures and dividing by six; the summary measure is the weighted average of the odds ratios from separate models for each individual injection outcome.
[c]Ordinal measures: 1, 'never'; 2, 'rarely'; 3, 'less than half the time'; 4, 'about half the time'; 5, 'more than half the time'; 6, 'almost always'; 7, 'always'.
[d]Response categories were reverse-coded so that higher values represent greater risk.
[e]Response categories for partners shared injection equipment with: 1, 'none'; 2, 'almost none'; 3, 'less than half'; 4, 'about half'; 5, 'more than half'; 6, 'almost all'; 7, 'all'.

sex with main partners decreased 46% more among PEI than VDI participants. The intervention design assumed that behavior change with steady partners would translate into behavior change among non-steady partnerships; therefore, PEI messages focused mostly on steady partnerships. In retrospect, this assumption may be inaccurate, but could explain why the PEI produced greater, although non-significant, decreases in unprotected sex only with steady partners.

All injection and several sexual risk behaviors decreased significantly at follow-up compared with baseline among PEI participants; however, decreases also occurred among VDI participants, emphasizing the importance of measuring efficacy relative to a concurrent control group. Considering the possibility that participants in both arms learned through successive assessments that underreporting risk behaviors shortened the interview, we compared responses on repeated baseline assessments from participants who had to be reassessed when 3 months had lapsed before they were enrolled. No consistent downward trends in self-reported risk behaviors were found.

Failure to detect significantly greater risk reductions among PEI versus the VDI participants may be caused by features inherent in the trial's design. For example, by giving all participants identical pre and posttest counselling before enrollment, and making condoms, bleach kits, HIV and HCV-related educational pamphlets and medical

Table 4. Comparison of 6-month changes in sexual risk behaviors among 15–30-year-old injection drug users participating in a peer education intervention or video discussion intervention, 3rd Collaborative Injection Drug Users Study/Drug Users Intervention Trial, 2002–2004.

No. of acts done without condom	PEI arm 6-month change RR (95% CL)	VDI arm 6-month change RR (95% CL)	Intervention effect[a] (change in PEI/VDI) RR (95% CL)	*P* value
Total acts with all partners	0.67 (0.55, 0.83)	0.77 (0.62, 0.95)	0.90 (0.67, 1.21)	0.486
Vaginal sex with main partner	0.65 (0.52, 0.81)	0.72 (0.58, 0.90)	0.90 (0.65, 1.23)	0.489
Vaginal sex with non-main other steady	0.72 (0.36, 1.45)	0.56 (0.29, 1.10)	1.10 (0.41, 2.97)	0.849
Vaginal sex with casual/sex trade partner(s)	0.85 (0.52, 1.38)	0.69 (0.43, 1.10)	1.17 (0.60, 2.29)	0.648
Anal sex with main partner	0.52 (0.31, 0.85)	0.84 (0.56, 1.25)	0.66 (0.35, 1.23)	0.192[b]
Anal sex with non-main other steady	0.13 (0.01, 1.13)	0.82 (0.25, 2.67)	0.22 (0.02, 2.05)	0.185
Anal sex with casual/sex trade partner(s)	0.88 (0.43, 1.83)	0.29 (0.14, 0.59)	3.15 (1.13, 8.79)	0.028[b]

CL, Confidence limit; PEI, peer education intervention; RR, risk ratio; VDI, video discussion intervention.
[a]Estimates result from negative binomial regression models with inclusion of a random intercept to account for within-subject correlation in which city, race, sex, cohort size, age, and men who have sex with men or women who have sex with women status were considered as potential covariates; women who have sex with women and cohort size were not significant in any model.
[b]To account for excessive zero responses and extreme values in the data, we reanalysed the data using zero-inflated negative binomial models (STATA software, version 8) with robust variance estimates and two components, a logit component of the zero probability and a negative binomial component of the frequency count. We observed a significantly greater reduction in the frequency component of 'unprotected anal sex with a main partner' among PEI participants (RR 0.54; 95% CL 0.33, 0.87), and there was no longer a significant difference in 'unprotected anal sex with casual/sex trade partner(s)' by trial arm using this mixture model.

and drug treatment referrals available in both interventions, all participants received similar information. An overly powerful control condition has the effect of minimizing the relative efficacy of the intervention, which has been observed in previous behavioral intervention trials [28]. Although this trial was not designed to measure community-level effects of the PEI, such an effect was desired. If randomization placed network members into opposing trial arms, PEI participants may have practised what they learned with their VDI arm peers. Consequent reductions in risk behavior among VDI participants would result in underestimating the effect of the PEI on behavior change compared with the control arm.

Our study was limited by the fact that participants had to return for test results to learn of their eligibility, and then had to return for a third visit, sometimes weeks later, for random selection. Consequently, many eligible participants were lost in the process. We thus lost statistical power to detect differences in less prevalent behaviors, such as unprotected sex. Second, intensive risk-reduction training exclusive to the PEI may have caused PEI participants to feel greater pressure than VDI participants to underreport risk behaviors at follow-up in an effort to please their trainers, thus biasing results in favor of the PEI. The use of ACASI to minimize socially desirable responding, and seeing an intervention effect for injection but not sexual behaviors, makes this bias appear unlikely. Third, attrition could have biased results, but 83% returned for at least one follow-up visit and we observed no significant differences between returners and non-returners. Fourth, it is unknown whether our sample is representative of all young adult IDU; however, by employing multiple recruitment strategies in five cities, a broad cross-section of IDU was included. Fifth, intention-to-treat analyses are subject to bias if intervention attendance is low or uneven across arms. Although only 56% of participants overall attended all six intervention sessions, all participants attended at least the first session and attendance at each of the remaining sessions was reasonably high; on average 77% (range 68–100%) of PEI participants and 78% (range 71–100%) of VDI participants attended each session. Furthermore, attendance was similar across trial arms. Finally, sustainability of the intervention effect may not have been measurable in a 6-month follow-up period.

The strengths of this study include the use of a randomized controlled trial design with a dose-equivalent control condition. This design minimized the effect of merely paying attention to participants assigned to the intervention group (Hawthorne effect), which could be significant in marginalized populations such as young IDU. We examined multiple injection and sexual behavioral outcomes, plus a biological outcome, seeking consistency across outcomes to weight empirical evidence of an intervention effect. As behavioral intervention efficacy often degrades over time, we averaged efficacy over a 6-month period to be conservative. Finally, our multisite design provides better generalizability than a single-site trial.

This peer education intervention offers a means for substantially reducing injection risk behaviors among IDU, particularly those who have been injecting for a short time and are at high risk of blood-borne infections. The potential community-wide effects of training peer educators could further impact the spread of HIV and HCV among young IDU. Intensifying the intervention to eliminate, rather than reduce, injection risk may be required to decrease HCV incidence among IDU significantly.

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