

Results From a Randomized Controlled Trial of a Peer-Mentoring Intervention to Reduce HIV Transmission and Increase Access to Care and Adherence to HIV Medications Among HIV-Seropositive Injection Drug Users

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Background: There is a lack of effective behavioral interventions for HIV-positive injection drug users (IDUs). We sought to evaluate the efficacy of an intervention to reduce sexual and injection transmission risk behaviors and to increase utilization of medical care and adherence to HIV medications among this population.

Methods: HIV-positive IDUs (n = 966) recruited in 4 US cities were randomly assigned to a 10-session peer mentoring intervention or to an 8-session video discussion intervention (control condition). Participants completed audio computer-assisted self-interviews and had their blood drawn to measure CD4 cell count and viral load at baseline and at 3-month (no blood), 6-month, and 12-month follow-ups.

Results: Overall retention rates for randomized participants were 87%, 83%, and 85% at 3, 6, and 12 months, respectively. Participants in both conditions reported significant reductions from baseline in injection and sexual transmission risk behaviors, but there were no significant differences between conditions. Participants in both conditions reported no change in medical care and adherence, and there were no significant differences between conditions.

Conclusions: Both interventions led to decreases in risk behaviors but no changes in medical outcomes. The characteristics of the trial that may have contributed to these results are examined, and directions for future research are identified.

Key Words: HIV prevention intervention, injection drug use, randomized controlled trial, seropositive, sexual risk behavior

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Injection drug use is a major risk factor for transmission of HIV in the United States. Although the proportion of injection drug users (IDUs) among HIV-positive persons has decreased over time, the Centers for Disease Control and Prevention (CDC) reported that, at the end of 2004, IDUs accounted for 24% of existing AIDS cases in the United States (30% if men who have sex with men [MSM] and inject drugs are included).¹ By gender, 34% of overall AIDS cases among women and 21% among men are attributed to drug injection (29% among men if MSM IDUs are included).¹ Recent initiatives in the United States have emphasized the need to

develop science-based prevention interventions for HIV-positive persons.^{2,3} Although many people decrease their risk behaviors after learning that they are HIV-positive,^{4,5} a significant number of people across risk groups continue to engage in or relapse to unsafe sexual and injection risk practices.^{6–8} HIV-positive IDUs are an especially important group for prevention efforts because they can transmit HIV to their partners through sex and injection behaviors and they are vulnerable to other infections through both routes.

Numerous behavioral interventions have been shown to reduce injection risk among IDUs.⁹ Studies have shown strong independent effects of unprotected sexual behaviors as risk factors for HIV seroconversion among IDUs,^{10,11} which is important because HIV prevention interventions for IDUs have shown greater success in reducing injection risk behavior than sexual risk behavior.^{12–14} When looking at interventions for HIV-positive persons (not just IDUs), a recent meta-analysis found that these interventions have been effective at reducing sexual risk and sexually transmitted infections but not effective at reducing needle sharing, although only 3 studies contributed data to the findings about needle sharing, suggesting a lack of power to look at this outcome using meta-analytic techniques.¹⁵ To date, there has been only 1 behavioral intervention trial targeting HIV-positive IDUs, and this was a small trial ($n = 90$) focused on reducing sex and injection risk behavior of methadone-maintained IDUs.¹⁶ The authors reported a significantly greater reduction by the intervention participants compared with those in the control condition when the sex and drug risk were analyzed together.¹⁶ For comprehensive risk reduction, an intervention focusing on sexual and injection risks of community-based HIV-positive IDUs is needed.

In addition to their risk reduction challenges, HIV-positive IDUs struggle with accessing and utilizing medical care and adhering to HIV medications. HIV-positive IDUs have been consistently found to be less likely to receive HIV primary care and highly active antiretroviral therapy (HAART),^{17–19} more likely to lack health insurance,²⁰ and more likely to be hospitalized²¹ than non-IDUs. For those HIV-positive IDUs who do initiate HAART, some studies have shown that injection drug use is associated with decreased levels of adherence and attendance at HIV primary care clinics.^{22,23} In contrast, other studies have shown no association between injection drug use and adherence after adjustment for a variety of potential confounding variables.^{24,25}

There are no effective published interventions that have been designed to address, in an integrated manner, utilization of medical care, adherence to HIV medications, and behavioral risk reduction among HIV-positive IDUs. To address this gap, in 1999, the CDC, the Health Resources and Services Administration (HRSA), and research teams in 4 cities in the United States developed and implemented the Interventions for Seropositive Injectors—Research and Evaluation (INSPIRE) project. The INSPIRE project was designed to test the efficacy of an integrated behavioral intervention intended to (1) reduce sexual transmission risk behavior, (2) reduce injection transmission risk behavior, (3) increase utilization of IV primary care, and (4) increase adherence to HIV medications.

METHODS

Details of the development of the intervention and the study methods have been described previously.²⁶ An overview of recruitment and assessment procedures, intervention content and delivery, intervention quality assurance, participant retention, and intervention outcomes is provided here. All research activities were approved in advance by institutional review boards at the collaborating sites and the CDC.

Recruitment and Eligibility

Between August 2001, and October 2003, cohorts of HIV-positive IDUs were recruited from a variety of community venues in Baltimore, Miami, New York, and San Francisco (Fig. 1). Potential participants were screened by telephone or face-to-face by trained interviewers using a computerized screening program. Eligible participants were at least 18 years old, injected drugs in the past year, had at least 1 opposite-sex sexual partner in the past 3 months, self-identified as HIV-positive, were willing to have their HIV serostatus confirmed through an oral HIV-antibody test, agreed to a blood draw for CD4 cell count and viral load testing, had not been enrolled in the cross-site pilot study and were not currently enrolled in an intervention study conducted by a principal investigator, lived within the study area and were willing to provide contact information, could communicate in a group in English (although assessment could occur in Spanish), and indicated availability to attend the first intervention session.

Baseline Visit and Randomization

Eligible participants were scheduled for a baseline visit during which they provided informed consent, provided an oral fluid sample for confirmatory HIV-antibody testing (OraSure; OraSure Technologies, Bethlehem, PA), provided 2 tubes of blood for CD4 cell count and viral load testing, and completed an audio computer-assisted self-interview (A-CASI).²⁷ Regarding blood samples, 1 tube of blood was sent to the CDC HIV Serology Laboratory for HIV viral load testing. HIV RNA was quantified by reverse transcription polymerase chain reaction (Amplicor Version 1.5; Roche Diagnostics, Branchburg, NJ), with a detection range of 400 to 750,000 copies/mL. The second tube of blood was sent to the CDC Immunophenotyping Laboratory for lymphocyte subset analysis using traditional flow cytometry to obtain a CD4 percentage (CD%) and the True Count bead method (Becton Dickinson, San Jose, CA) to calculate CD4 cell count. In separate optional visits, participants were provided their CD4 cell count and viral load results using a standard script to avoid providing medical advice. Results also were provided to medical providers with permission from participants.

During their baseline appointment, up to 30 participants were invited to return for the prescheduled randomization session. When the cohort of participants arrived for the first intervention session (cohort size range: 8 to 25 people), each individual was randomly assigned to 1 of the 2 trial arms. One staff member at each site who was not an intervention facilitator used a computer program to assign participants to 1 of the 2 intervention conditions. Because we anticipated that approximately two thirds of our participants would be men, the randomization program stratified participants by gender using

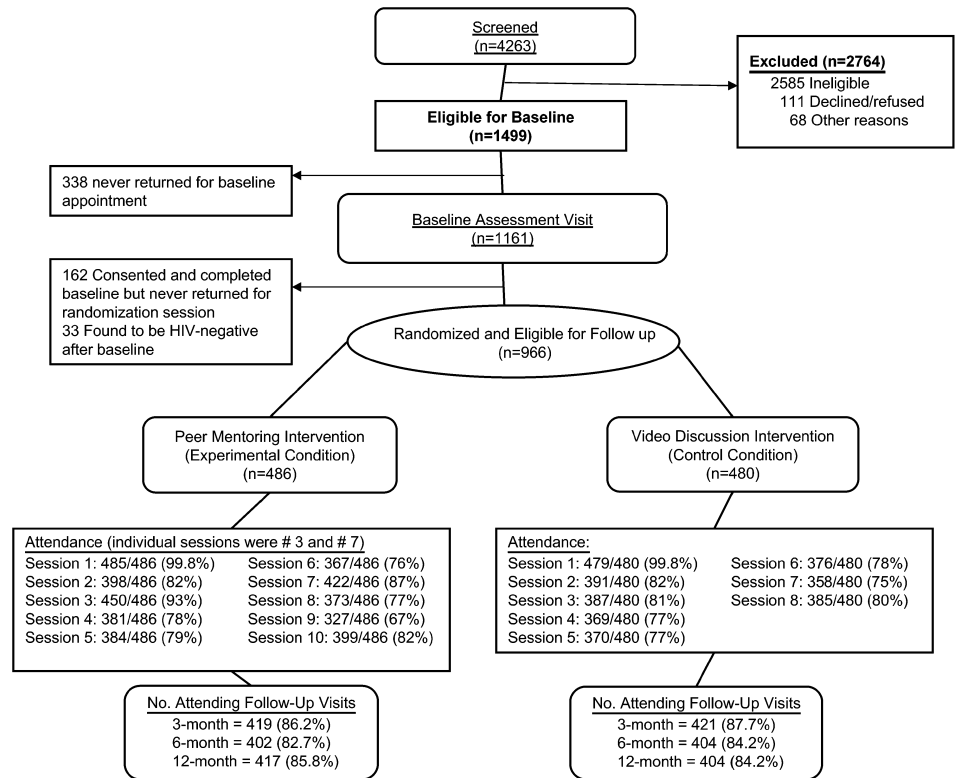


FIGURE 1. Flow diagram of the INSPIRE study visits and participation rates, August 2001 through March 2005.

a block size of 6 for men and 4 for women to try to achieve similar gender ratios across arms and to minimize the likelihood of an intervention group containing only 1 woman. When the number of participants who presented for randomization was <8, the first intervention session for that cohort was re-scheduled. During the study, 70 cohorts of eligible participants were randomized into 1 of the 2 trial arms (18 cohorts in each city, except 16 in New York City as a result of delayed start-up after the September 11, 2001 terrorist attacks).

Follow-Up Data Collection

Study outcomes were assessed through A-CASI and blood draws at follow-up visits 3 (no blood), 6, and 12 months after intervention. Participants were reimbursed for their time and effort for participating in assessments and intervention sessions. The collection of follow-up data ended in March 2005, and all participant identifiers and contact information were destroyed shortly thereafter.

Intervention Conditions and Quality Assurance

The peer mentoring intervention (PMI, the intervention condition) was developed based on a combination of theories and concepts, including empowerment,^{28,29} peer leadership or advocacy;³⁰ Social Learning Theory (SLT);³¹ Social Identity Theory;³² and the Information, Motivation, and Behavioral Skills (IMB) Model.³³ Participants were told during the first session that we wanted to help them try out a new social role as informal peer mentors and that learning this role would help them to protect themselves and their communities (using the slogan “power to protect”). This concept was developed from

research showing that taking on such a prosocial role supports risk reductions and was consistent with formative work at all 4 sites showing that HIV-positive IDUs were seeking such a role.²⁶ The PMI was revised through extensive focus group and pilot testing activities and feedback from community advisory boards. Sessions were delivered twice a week for 5 weeks and included 7 group sessions (led by a male facilitator and a female facilitator), 2 individual sessions (matched by gender in most cases), and 1 “peer volunteer activity” (PVA), during which participants went to a local service organization for 2 to 4 hours to observe, participate, and practice peer mentoring skills. For the topics of the sessions, the first session focused on setting group rules and the power of peer mentoring, 2 group sessions and 1 individual session focused on utilization of HIV primary care and adherence, and 3 group sessions and 1 individual session focused on sex and drug risk behaviors. Risk messages were communicated using posters and handouts with risk hierarchies that ordered sex behaviors and injection behavior on 2 separate pyramids from no risk to highest risk. Participants were encouraged to identify their risk behavior and move as far down the risk pyramid (in a less risky direction) as possible. Individualized risk plans based on the hierarchies were discussed during the individual session focusing on sex and injection behaviors. The final group session focused on review and reinforcement of motivation and skills for behavior change and ended with a graduation ceremony. For both conditions, a resource table that provided information about local services available for medical care, support groups, drug treatment, and prevention resources such as pamphlets and male and female condoms was available during and after every session.

Participants in the video discussion intervention (VDI, the control condition) took part in 8 group sessions over 5 weeks. The VDI condition provided nearly equal attention (matching the 7 groups and PVA but not the 2 individual sessions) and controlled for experimental demand (by providing 1 session of basic HIV prevention information). For all but session 1, the VDI sessions were led by the same 2 facilitators who led the PMI. Because the first sessions of the VDI and the PMI occurred simultaneously after randomization, the first VDI session was led by 2 different facilitators who were introduced as “HIV experts” and provided the basic HIV prevention information. Participants in the VDI watched documentary or self-help videos focused on issues relevant to HIV-positive IDUs (eg, prejudice and discrimination, getting a job, incarceration, Red Cross safety tips, overdose prevention), followed by facilitated discussion. Topics directly related to the intervention outcomes were avoided or minimized. As noted, community resources and risk reduction information and tools were available at every VDI session.

To aid in supervision and to allow for quality assurance, all sessions in both conditions were audiotaped. To conduct quality assurance, 1 session from each of the 70 cohorts from each condition was chosen at random for examination. A tape from each site from the same condition/session from each cohort was rated for adequacy of intervention delivery (70 cohorts \times 2 conditions = 140 session tapes). Every selected tape was reviewed and rated by 2 senior researchers from separate sites or the CDC. Tapes were rated for whether or not facilitators adequately delivered or facilitated the components of each session as described in the intervention manual (the number of components rated for each session ranged from 5 to 11). The overall percentage of session components that were rated acceptable was high (91%), and overall agreement among raters for each component also was high (95%).

Reimbursement

Participants were reimbursed for their time and effort in the following amounts: US \$30 to \$50 for baseline and follow-up assessments (with amount increasing over time), \$20 for each intervention session, \$5 for agreeing to use a medication event monitoring system (MEMS) cap to measure adherence (data not reported here), and \$5 for each follow-up appointment in which the participant returned with the MEMS cap. The maximum amount a participant could have received over the approximately 15-month study period was \$360 (\$380 for consistent MEMS cap carriers).

Measures

Multiple outcome measures were assessed to determine whether the intervention had an effect on decreasing sexual and injection transmission risk behavior or increasing utilization of care and adherence to HIV medications. Methods employed to enhance the validity of participants' self-reported behaviors included (1) using A-CASI to minimize interviewer bias and socially desirable responding, particularly for stigmatized behaviors;³⁴⁻³⁶ (2) excluding intervention facilitators from follow-up assessment activities to avoid a booster effect or biased responses related to intervention messages; and (3) using recall aids (eg, calendars) and a relatively short

recall period (3 months) to maximize recall on assessments. In addition, we collected data regarding participants' evaluation of the intervention and measurement of recognition and recall of intervention messages.

Sexual Behaviors

Participants reported specific sexual behaviors, whether these behaviors were protected, and partner characteristics for their 3 most recent partners (4 partners if the participant had a main partner who was not included among the first 3 partners). Participants with more partners then answered questions about these other partners, with the partners aggregated by perceived partner serostatus (eg, questions were asked about HIV-negative partners as a group, then about HIV-positive partners, and, finally, about unknown serostatus partners). Two categories for partner serostatus were created (HIV-positive or HIV-negative/unknown serostatus). For our outcomes, we were particularly interested in decreasing sexual risk behavior with HIV-negative or unknown serostatus sex partners. The outcome variable for sexual risk was dichotomized to indicate whether or not participants reported any unprotected vaginal/anal sex in the past 3 months with their HIV-negative or unknown status partners. More detailed information on the sexual risk of study participants is provided in other previously published articles focusing on women³⁷ and men³⁸ and in another article in this special supplement focusing on gay and bisexual men.³⁹

Injection Behaviors

Participants were asked about the number of injection risk behaviors in the past 3 months, including sharing of syringes and paraphernalia (cottons, cookers, and rinse water), with injection partners by the partner's serostatus (HIV-positive, HIV-negative, or unknown serostatus). The key injection risk behavior outcome was whether, in the past 3 months, the participant had lent a syringe that he or she had previously used to any HIV-negative or unknown serostatus partners or whether the participant had shared cottons, cookers, or rinse water with any HIV-negative or unknown serostatus partners.

Utilization of HIV Care

Participants were asked about number of primary HIV care visits in the past 6 months. HIV primary health care visits were defined as “a visit to a doctor or medical provider to have a check up on how you're doing with your HIV or AIDS, (which may include) discussion about HIV or AIDS medications, or blood test results.” The outcome for utilization of care was whether a participant reported 2 or more HIV primary health care visits in the past 6 months, based on the definition from the HIV Cost and Services Utilization Study of optimal outpatient service use for HIV-positive persons.⁴⁰

Adherence to HIV Medications

We measured participant self-report of number of doses of antiretroviral medication prescribed and number of doses missed in the previous day and the previous week. Adherence for each participant was defined as number of doses taken divided by number of doses prescribed. For our outcome, good

adherence was further defined as having taken 90% of anti-retroviral medications in the prior 7 days. Adherence measured in this manner has been shown to be correlated with HIV viral load.⁴¹

Potential Covariates

As described in this report, certain variables were selected a priori for 1 of the 4 multivariate models testing the effect of the intervention on our 4 outcomes. Sociodemographic variables were mostly dichotomous and included city, biologic sex, age (continuous), race/ethnicity (African American, Hispanic, white, and other), education (less than high school vs. high school graduate), time since HIV diagnosis (continuous), homelessness in the past 12 months, current unstable housing, living with any children, having a main partner, disclosing HIV status to all 3 most recent partners versus disclosing to some or none, having insurance, and attending outpatient drug treatment in the past 6 months. Regarding substance use, participants were asked separately about their use of a variety of injection and noninjection drugs in the past 3 months.

Multi-item scales included in some of the analyses included depression (7 items from the Brief Symptom Inventory;⁴² $\alpha = 0.90$), self-perceived health status (the physical functioning subscale of the Medical Outcome Study approach,⁴³ 7 items; $\alpha = 0.87$), communications between provider and patient (13 items;⁴⁴ $\alpha = 0.95$), social support (5 items adapted from Barrera;⁴⁵ $\alpha = 0.87$), empowerment (28 items;⁴⁶ $\alpha = 0.76$), taking control of health care (4 items developed by study team; $\alpha = 0.63$), and self-efficacy for taking HIV medications as prescribed (13 items developed by study team; $\alpha = 0.96$). Single-item measures included in some of the analyses included perception of health in past 6 months (5-point Likert response format ranging from “poor” to “excellent”) and spirituality (“How important is spirituality or religion in your life?”; 5-point Likert response ranging from “not at all” to “very”).

Participant Evaluation of the Interventions

At the 3-month follow-up, participants were asked to rate the intervention on 13 items that assessed perceived effects of the intervention, how they liked the group leaders, and their overall impression of the intervention. These items were adapted from items used to evaluate a previous intervention for HIV-positive MSM.⁴⁷ Items were rated on a 5-point Likert-type scale (ranging from strongly disagree [1] to strongly agree [5]), with higher scores indicating more positive evaluation of the intervention.

Recognition and Recall of Intervention Messages

Also, at the 3-month follow-up, participants were asked if they recognized 3 intervention slogans or acronyms (yes/no for each), and if they recognized them, whether they remembered the meaning of the slogan or acronym (yes/no), and if they remembered the meanings, if they could select the correct meaning from 4 choices. The purpose of this test was to check for cross-contamination of messages, which was a possibility because of the peer mentoring encouraged in the intervention arm of the study. In addition to these 3 items,

a fourth item using a made-up acronym was tested to see whether participants had a tendency toward endorsing recognition of these items.

Statistical Analyses

Sample size calculations were performed for the sexual risk outcome and were based on previous formative research showing a prevalence of 25% of HIV-positive IDUs reporting unprotected anal or vaginal sex with an HIV-negative or unknown status partner.⁴⁸ Estimating 20% attrition over the 12-month follow-up period and assuming 500 participants randomized to each arm, the projected and achieved sample size had 82% power ($\alpha = 0.05$) to detect a 7.5% absolute reduction in the PMI group compared with the VDI group for the sex outcome (30% relative difference). All statistical tests were performed at the 5% significance level, and analyses were performed using SAS software, version 9.1 (SAS Institute, Cary, NC).

First, the baseline data were examined for between-condition differences using the Fisher exact test for binary variables, χ^2 tests for categorical variables, and 2-sample *t* tests and Wilcoxon rank sum tests for count and continuous variables. The purpose of these tests was to detect substantially unbalanced baseline variables for which to control in subsequent analyses. No differences were found between the groups.

The following 4 binary variables were selected as primary outcomes of interest: (1) any unprotected anal or vaginal sex with HIV-negative or unknown serostatus partners; (2) any lending syringes to HIV-negative or unknown serostatus partners or any sharing of cookers, cottons, or other drug paraphernalia with HIV-negative or unknown serostatus partners; (3) having 2 or more health care visits within the previous 6 months; and (4) having a 90% or better adherence to prescribed medications over a 1-week period. The key predictor variable of interest was the condition assignment (PMI or VDI). The intention-to-treat assumption was made for all analyses with this condition variable. Initially, mixed effects models with fixed time and condition effects (and their interaction) and random subject effects were fit to examine changes over time in each outcome variable.

For each of these primary outcomes, a set of candidate explanatory variables was then selected on an a priori basis. These candidate variables included core baseline demographic variables (city, biologic sex, age, race and ethnicity, and education) and other factors suggested by prior research (time since HIV diagnosis, homelessness in the past 12 months, current unstable housing, and baseline depression). They also included variables specific to 3 of the 4 outcomes (all but injection risk): (1) high-risk sex (spirituality, having MSM sex, living with family, living with children, having a main partner, and disclosure of HIV status to partner), (2) obtaining health care (insurance, outpatient drug treatment program, perception of health in past 6 months, viral load, and CD4 count), and (3) adherence (communications between provider and patient, taking control of health care, self-perceived health status, cocaine use, alcohol consumption, self-efficacy for taking HIV medications as prescribed, social support, baseline depression, empowerment, and baseline high-risk sex and injection drug use).

Logistic regression models were constructed with these outcomes as the response variables to examine whether they were affected by the condition received. First, simple logistic regression models were constructed with only condition assignment; condition assignment plus a single covariate; and condition assignment, a single covariate, and the interaction between condition and the covariate. These models were used to check for the significance of condition and to screen for more promising candidate predictor variables. Additional multivariate logistic regression analyses were performed using all the variables and only the most promising candidate predictor variables, in conjunction with the backward and stepwise selection procedures. Parsimonious models were aimed for as well as consistency in the covariates selected over time, with the primary focus being on studying the impact of condition on the chosen outcome variables. Finally, we regarded missing data as being missing at random, and simple imputation models gave comparable results.

RESULTS

A total of 4263 people were screened; 1499 HIV-positive IDUs were found to be eligible, and 1161 completed the baseline assessment (see Fig. 1). A total of 966 eligible IDUs were randomized into the trial. Regarding comparisons between the 966 randomized participants versus those who were not randomized ($n = 195$), there were no significant differences between these 2 groups on most demographic variables or for any risk or outcome variables. The percentage of participants who were eventually randomized was different by race, however, with Hispanics being most likely to be lost between baseline and randomization (87% of enrolled African Americans were randomized, 79% of whites, 74% of Hispanics, and 84% of other races; $\chi^2(3, 1141) = 21.68$; $P < 0.001$).

Of the participants randomized, 486 were assigned to the PMI condition and 480 were assigned to the VDI condition. There were no significant baseline differences between these 2 groups. The characteristics of the randomized participants are shown in Table 1. Average session attendance by PMI participants was 82% (range: 67% to 100%), and that by VDI participants was 81% (range: 75% to 100%) (see Fig. 1 for attendance at specific sessions). Overall, the mean number of sessions attended in the PMI group was 8.2 sessions ($SD = 2.2$), and 35% attended all 10 sessions. The mean number of sessions attended in the VDI group was 6.5 sessions ($SD = 1.9$), and 40% attended all 8 sessions.

Follow-up assessments were completed by at least 82% of participants at every time point, and there were no differences in attrition between conditions (see Fig. 1). For each follow-up, differences between those who returned for follow-up and those who were lost to follow-up were tested for study design, demographic, and risk behavior variables. In multivariate logistic regression, loss to follow-up at 3 months was associated with lower session attendance and the following characteristics as measured at baseline: younger age, lower income, and study site (Miami participants were less likely to be retained) ($P < 0.05$). At 6 months, loss to follow-up was associated with lower session attendance, lower income,

and being male ($P < 0.05$). At 12 months, lower session attendance, being male, and study site (Miami participants were less likely to be retained) were associated with loss to follow-up ($P < 0.05$).

Participant ratings taken at the 3-month follow-up visit of self-perceived intervention effects, evaluation of group leaders, and overall assessment of the intervention are shown in Table 2. Participants in the PMI condition rated many aspects of their intervention condition more favorably than those in the VDI condition, although overall ratings in both groups were highly skewed in the favorable direction. Regarding recognition, reported recall, and accurate identification of 3 key intervention slogans or acronyms, PMI participants reported greater recognition and reported greater recall on all 3 items compared with VDI participants (Table 3). PMI participants also demonstrated greater recall by accurately identifying the meaning of the slogan or acronym on 2 of 3 items. For the made-up acronym, more than twice as many PMI (30%) as VDI (14%) participants reported recognizing the items, but there was no difference in reported recall among those claiming recognition of this item (see Table 3).

Effects of the Intervention

For the primary sexual and injection risk variables, the risk behaviors in both groups decreased over time compared with baseline ($P < 0.01$), but the amount of decrease did not differ significantly between groups. Table 4 shows the proportions of subjects reporting sex or injection risk behavior at 3-, 6-, and 12-month follow-ups in the PMI and VDI conditions. We report the results of the backward regression models as the main results; Table 4 shows the adjusted odds ratios with 95% confidence intervals for the effect of condition assignment on the main sex and injection outcome variable at 3-, 6-, and 12-month follow-ups. The condition assignment was not significant for either of the 2 primary risk outcome variables at any time point. The models were adjusted for various explanatory covariates. Baseline outcome values tended to be significant predictors of subsequent behavior. Results for models constructed by other methods gave similar results.

For utilization of health care, rates were relatively stable or slightly decreased over time in both groups (not significantly), although adherence slightly increased over time in both groups (significantly at 6 months [$P = 0.03$] and 12 months [$P = 0.01$]). Table 5 shows the proportions of subjects reporting more than 2 care visits in the past 6 months and those on medications who reported 90% adherence or more in the past 7 days at 3-month (adherence only), 6-month, and 12-month follow-ups in the PMI and VDI conditions. We report the results of the backward regression models as the main results; Table 5 shows the adjusted odds ratios with 95% confidence intervals for the effect of condition assignment on the main utilization and adherence outcome variable at 3-month (adherence only), 6-month, and 12-month follow-ups. Similar to the results for risk behaviors, there were no statistically significant differences between the 2 conditions at any time point. The models were adjusted for various explanatory covariates. Baseline outcome values tended to be significant predictors of subsequent behavior (not shown). Results for models constructed by other methods gave similar results.

TABLE 1. Baseline Characteristics of HIV-Positive IDUs Enrolled in the INSPIRE Study by Trial Arm (Baltimore, Miami, New York City, and San Francisco), 2001 to 2005

	Total (n = 966)* %	Enhanced/PMI (n = 486)* %	Control/VDI (n = 480)* %
City			
Baltimore	265 (27.4)	134 (27.6)	131 (27.3)
Miami	260 (26.9)	128 (26.3)	132 (27.5)
New York	217 (22.5)	111 (22.8)	106 (22.1)
San Francisco	224 (23.2)	113 (23.3)	111 (23.1)
Mean age, years (SD)	42.4 (6.6)	42.6 (6.3)	42.1 (6.8)
Gender			
Male	589 (61.0)	299 (61.5)	290 (60.4)
Female	348 (36.0)	171 (35.2)	177 (36.9)
Transgender	29 (3.0)	16 (3.3)	13 (2.7)
Race/ethnicity			
Black	636 (65.8)	314 (64.6)	322 (67.1)
Hispanic	148 (15.3)	76 (15.6)	72 (15.0)
White	88 (9.1)	45 (9.3)	43 (9.0)
Other	72 (7.5)	38 (7.8)	34 (7.1)
Sexual orientation			
Heterosexual	678 (70.2)	342 (70.4)	336 (70.0)
Gay/homosexual	56 (5.8)	28 (5.8)	28 (5.8)
Bisexual	172 (17.8)	81 (16.7)	91 (19.0)
Other	50 (5.2)	31 (6.4)	19 (4.0)
Education			
<High school	416 (43.1)	201 (41.4)	215 (44.8)
High school	310 (32.1)	157 (32.3)	153 (31.9)
Some college	178 (18.4)	92 (18.9)	86 (17.9)
College degree or more	57 (5.9)	33 (6.8)	24 (5.0)
Income			
<\$5000	492 (50.9)	250 (51.4)	242 (50.4)
\$5000 to \$9999	310 (32.1)	153 (31.5)	157 (32.7)
\$10,000 to \$19,999	106 (11.0)	55 (11.3)	51 (10.6)
\$20,000 or more	26 (2.7)	13 (2.7)	13 (2.7)
Currently unemployed	916 (94.8)	456 (93.8)	460 (95.8)
Currently homeless (% yes)	100 (10.4)	51 (10.5)	49 (10.2)
Homeless past year (% yes)	313 (32.4)	148 (30.5)	165 (34.4)
Lifetime incarceration (% yes)	687 (71.1)	358 (73.7)	329 (68.5)
Recent incarceration (past 6 months) (% yes)	240 (24.8)	133 (27.4)	107 (22.3)
Primary outcomes			
UVA with HIV-negative/unknown serostatus partners (% yes)	255 (27.2)	133 (28.0)	122 (26.4)
Lent a needle to or shared drug paraphernalia with HIV-negative/unknown serostatus partners (% yes)	271 (28.7)	136 (28.6)	135 (28.8)
Utilized HIV care 2 times or more in the past 6 months (% yes)	718 (78.4)	362 (78.7)	356 (78.1)
90% or greater adherence to HIV medications in the past 7 days (% yes)	375/484 (77.5)	193/248 (77.8)	182/236 (77.1)

*Denominators differ for some cells due to missing data or skip patterns.
UVA indicates unprotected vaginal or anal intercourse.

DISCUSSION

The PMI and VDI were well attended and well liked by participants. Although the PMI was rated more favorably than the VDI, condition assignment was not associated with significantly differential effects for any of the 4 main outcomes. For sex and injection risk behaviors, both groups

decreased significantly from baseline, whereas for utilization of care and medication adherence, both groups were relatively unchanged over time (with slight increases in adherence). These findings highlight some of the challenges of motivating behavior change and differentially motivating behavior change between conditions in a complex study with multiple

TABLE 2. Participant Evaluations of PMI and VDI at 3-Month Assessment, INSPIRE Study (Baltimore, Miami, New York City, and San Francisco), 2001 to 2005

	Enhanced (PMI) (n = 419)*		Control (VDI) (n = 420)*		P†
	Mean	SD	Mean	SD	
Intervention effects‡					
The program motivated me to think about my own sexual behavior	4.32	0.89	4.18	0.84	<0.001
The program motivated me to think about my own drug-using behavior	4.37	0.80	4.24	0.73	<0.001
The program motivated me to pay more close attention to my health and health care	4.40	0.82	4.28	0.75	0.001
The program motivated me to make positive changes in my life	4.37	0.74	4.25	0.75	0.01
The program helped me to meet other HIV-positive drug users whom I had things in common with	4.33	0.82	4.25	0.77	0.01
The program helped me to talk to other drug users about what I learned from this program	4.33	0.75	4.27	0.70	0.056
The program motivated me to find programs or resources in the community that were useful to me	4.26	0.75	4.17	0.78	0.06
Group leaders evaluation					
Group leaders were					
Knowledgeable	4.50	0.71	4.34	0.72	<0.001
Supportive	4.53	0.62	4.49	0.57	0.10
Respectful of the participants in the program	4.55	0.65	4.50	0.64	0.11
Role models	4.48	0.68	4.35	0.69	0.002
Overall assessment of intervention					
I learned a lot from this program	4.34	0.94	4.22	0.92	0.004
I would recommend this program to other HIV positive drug users	4.52	0.67	4.47	0.65	0.19

*Means and SDs based on those reporting. Missing responses ranged from 3 to 9 for each variable.

†P values are based on Mann-Whitney U tests for nonparametric data.

‡Response category ranged from strongly disagree (1) to strongly agree (5).

outcomes and a high-need population. It is important to understand our findings better to inform the field and improve the implementation and design of future HIV prevention intervention trials with vulnerable populations. It is particularly important to understand why both groups decreased sex and drug risk over time and if something common to our 2 conditions actually led to this change.

Recent meta-analyses of 12 intervention trials for HIV-positive persons found that certain intervention characteristics were associated with significant sexual risk reduction, including (1) being based on behavioral theory; (2) being focused on HIV risk behaviors in at least two thirds of sessions; (3) being delivered by health care providers or counselors (although delivery by peers was marginally

TABLE 3. Proportion of Participants Reporting Recognition, Recall, and Demonstrating Accurate Identification of Intervention Slogans/Acronyms from the PMI Condition at 3-Month Follow-Up, INSPIRE Study (Baltimore, Miami, New York City, and San Francisco), 2001 to 2005

Have You Heard the Phrase "Slogan"?	PMI % (n)	VDI % (n)	P
PMI slogan 1 ["power to protect"]			
Recognized the slogan (% yes)	70.2% (228/325)	46.1% (149/323)	<0.001
Recalled the meaning (% yes)	71.5% (163/228)	35.8% (53/148)	<0.001
Correctly identified the meaning (% yes)	84.0% (137/163)	66.0% (35/53)	0.005
PMI slogan 2 ["PALMS"]			
Recognized the slogan (% yes)	68.8% (223/324)	13.9% (45/323)	<0.001
Recalled the meaning (% yes)	64.6% (144/223)	29.5% (13/44)	<0.001
Correctly identified the meaning (% yes)	87.4% (125/143)	53.8% (7/13)	0.001
PMI slogan 3 ["CARE"]			
Recognized the slogan (% yes)	83.3% (270/324)	55.7% (180/323)	<0.001
Recalled the meaning (% yes)	70.7% (191/270)	48.3% (87/180)	<0.001
Correctly identified the meaning (% yes)	37.0% (70/189)	33.7% (29/86)	0.59
Made-up slogan ["FEAT"]			
Recognized the slogan (% yes)	29.6% (96/324)	13.9% (45/323)	<0.001
Remembered the meaning (% yes)	65.6% (63/96)	60.0% (27/45)	0.52

TABLE 4. Proportion of HIV-Positive IDUs Reporting Sexual or Injection Risk Behavior With Their HIV-Seronegative or Unknown Serostatus Partners by Intervention Condition at 3-, 6-, and 12-Month Follow-Up Assessments, INSPIRE Study (Baltimore, Miami, New York City, and San Francisco), 2001 to 2005

	Unprotected Vaginal or Anal Sex With HIV-Negative/Unknown Serostatus Partners			Lent a Needle to or Shared Drug Paraphernalia With HIV-Negative/Unknown Serostatus Partners		
	PMI % (n)	VDI % (n)	adjOR (95% CI)	PMI % (n)	VDI % (n)	adjOR (95% CI)
Baseline	28.0% (133/475)	26.4% (122/462)	—	28.6% (136/476)	28.9% (135/468)	—
3-month follow-up	15.2% (60/396)	13.7% (55/401)	1.22 (0.79 to 1.89)	9.7% (40/413)	12.0% (49/410)	0.78 (0.49 to 1.25)
6-month follow-up	13.0% (51/391)	10.9% (42/384)	1.32 (0.83 to 2.12)	7.3% (29/397)	10.6% (42/396)	0.68 (0.40 to 1.13)
12-month follow-up	11.3% (46/407)	11.2% (44/393)	1.01 (0.63 to 1.61)	5.8% (24/414)	6.6% (26/394)	0.77 (0.42 to 1.41)

Explanatory variables that were significant for at least 1 time point in the logistic regression models are listed. Various transformations and categorizations of some of the variables were considered. Sex risk: baseline sex risk, city, age, education, homelessness in past 6 months, baseline depression. Injection risk: baseline injection risk, city, age, education, having a regular place to stay.

adjOR indicates adjusted odds ratio; CI, confidence interval.

significant); (4) being delivered to individuals (although delivery in groups was marginally significant); (5) being delivered intensively (more than 10 session or more than 20 hours) over a longer duration (>3 months); (6) being delivered in settings where HIV-positive persons usually receive care or services; (7) providing skills building and practice; and (8) addressing a number of issues related to coping with HIV, including mental health, medication adherence, and HIV risk behavior.¹⁵ Although the design of our study incorporated many of these characteristics, potential differences include (1) delivery by near peers in noncare settings for at least 80% of the cohorts (some New York cohorts were in a methadone clinic, where patients also received HIV care); (2) the PMI condition was primarily conducted in groups (although we did provide 2 individual sessions so that participants could individualize a care plan and a risk plan), which decreased the time for individual skills building and practice across the 4 outcomes; and (3) given the

4 outcomes, there may not have been enough skills building and practice over time to affect each behavioral outcome. Interestingly, individual sessions were the most attended sessions in PMI.

The last 2 points highlight an intervention design issue faced by our team—developing an intervention that was not too long but that still addressed all 4 outcomes in a manner that matched the realities of the participants’ lives. For sexual and injection risk, not providing a more individualized focus may have hampered our ability to produce differences between the 2 groups, particularly given the eligibility criteria discussed elsewhere in this article. Regarding good utilization of care and adherence, there were high levels reported at baseline (both >75%). Thus, those participants not reporting adequate levels of health care resource use may have had other challenges or structural issues in their lives that were not amenable to change through an intervention focusing on individual behavior change. In addition to these intervention

TABLE 5. Proportion of HIV-Positive IDUs Reporting Adequate Utilization of Care or Medication Adherence by Intervention Condition at 3-, 6-, and 12-Month Follow-Up Assessments, INSPIRE Study (Baltimore, Miami, New York City, and San Francisco), 2001 to 2005

	Utilized HIV Care 2 Times or More in the Past 6 Months			90% or Greater Adherence to HIV Medications in the Past 7 Days		
	PMI % (n)	VDI % (n)	adjOR (95% CI)	PMI % (n)	VDI % (n)	adjOR (95% CI)
Baseline	70.7% (324/458)	69.0% (312/452)	—	77.8% (193/248)	77.1% (182/236)	—
3-month follow-up	NA	NA	NA	79.7% (169/212)	79.4% (173/218)	0.99 (0.56 to 1.76)
6-month follow-up	71.2% (282/396)	72.4% (289/399)	0.81 (0.57 to 1.14)	82.0% (168/205)	85.0% (170/200)	1.02 (0.53 to 1.96)
12-month follow-up	69.3% (286/413)	64.2% (253/394)	1.14 (0.82 to 1.58)	88.8% (174/196)	85.9% (182/212)	1.41 (0.66 to 2.98)

Explanatory variables that were significant for at least 1 time point in the logistic regression models are listed. Various transformations and categorizations of some of the variables were considered. HIV care utilization: baseline HIV care utilization, city, age, education, viral load levels, homelessness in past 12 months, having a regular place to stay. Adherence: baseline adherence, empowerment, ever drinking alcohol, self-efficacy for taking HIV medications, self-perceived health status, baseline sex risk.

adjOR indicates adjusted odds ratio; CI, confidence interval; NA, not applicable.

characteristics identified from the literature, there were 3 other domains that are important to consider in understanding our results: (1) participant characteristics and eligibility, (2) study design, and (3) other potentially relevant intervention characteristics.

Despite the fact that condition assignment was not associated with significantly differential effects for any of our 4 main outcomes, sex and injection behavior did change in both groups. The fact that reductions in risk behavior were reported in both groups of participants who have been HIV-positive for many years and despite potentially established behavioral patterns for sex and injection is worth further exploration. Many intervention enrollees came to the intervention trial wanting to obtain what is provided in the intervention (PMI) condition. Although this is not unique to this intervention trial, the fact that we had motivated participants in the control condition (VDI) was particularly challenging because of the unintended strength and impact of the VDI on participants.⁴⁹ This condition brought groups of persons together, knowing that they were all HIV-positive, and allowed them to form strong relationships with each other through watching and discussing videotapes relevant to their lives. Even though the intervention topics from the PMI were avoided after the first session of the VDI, this first session may have set a norm that led to more discussions about HIV outside of the sessions. In addition, qualitative data collected after the 12-month follow-up indicated that just being together with other HIV-positive persons and talking was reported by many participants to be a powerful experience.⁴⁹ At the graduation ceremony for each condition, site and CDC observers found the outpouring of emotions and appreciation of the study to be similar between conditions. Like participants in the PMI condition, some participants in the VDI groups dressed up for graduation, and participants were nearly unanimous in their praise for the group, the facilitators, and their overall INSPIRE experience. Thus, our research team did a good job of providing equal attention and support to this group, as evidenced by equal attendance and the quantitative and qualitative reports of participants. Given the isolation and lack of meaningful attention that this population often reported, this attention alone may have been powerful in helping participants in the control condition to make changes in their lives and to catalyze change in their sexual and injection risk. Supporting the importance of this attention is the fact that one of the more common requests at the end of each cohort, regardless of condition, was that the group be allowed to continue to meet.

Another potential design explanation for the patterns of change in our sex and drug risk data is that the repeated A-CASI assessments (or simply repeated assessments, regardless of method) with detailed questions about risk behaviors may have reduced reporting of risk over time and obscured any group differences. Assessments themselves can lead participants to reflect on their behaviors and can potentially lead to actual changes or changes in reporting. Also, the cognitive burden required to calculate risk behavior frequencies over a 90-day period may lead to a systematic underestimation, although we tried to reduce this by providing charts to help participants translate weekly activities into monthly totals. At

baseline, assessments averaged 87 minutes, whereas at the 12-month follow-up, the assessment averaged just longer than 1 hour. This could reflect learning about using the computer, learning by participants that reporting fewer partners would lead to a shorter assessment, or actual behavior change. The mean number of partners reported decreased from 6.5 (SD = 34.1) at baseline to 1.9 (SD = 9.0) at 12 months, but whether this is a real change or an assessment effect is hard to tease apart. We also found that the small number of people ($n = 24$) who reported an excess number of "refuse-to-answer" responses reported greater physical limitations and lower CD4 cell counts, suggesting that medical issues could account for some underreporting at follow-up.⁵⁰ Finally, both interventions may have heightened social desirability to report risk reduction, particularly in the context in which participants reported good experiences with the intervention, the facilitators, and the project. We tried to minimize this through the use of A-CASI and by not using facilitators to conduct follow-up assessments, but socially desirable responding may partly explain our results as well. Thus, having a comprehensive A-CASI could have affected the results through (1) personal reflection and behavior change, (2) learning patterns to shorten follow-up assessments, and (3) socially desirable responding. Designing a study to measure the potential assessment effect on an HIV prevention intervention is costly but crucial to further our understanding of the outcomes of behavioral trials. This design could be accomplished by adding another study arm that only receives an assessment at follow-up (with the assumption of equivalence at baseline).

A final study design issue was potential cross-contamination of the 2 conditions. Part of the task in the PMI was to talk to peers, particularly other HIV-positive IDUs, about what was being discussed in the intervention. Thus, it is likely that some participants in the VDI condition received mentoring and messages from participants in the PMI condition. This is supported by the data showing some recognition and accurate identification of key intervention slogans and acronyms by participants in the VDI condition. In addition, PMI participants might have actively sought out friends in the VDI condition who they knew were riskier, and it is these people to whom they provided peer mentoring, which would have decreased our ability to find an intervention effect. An alternative design to have avoided this problem might have been to implement the 2 conditions in different locations, although this design brings its own limitations.

Determining appropriate eligibility criteria and enrolling participants in an HIV prevention intervention trial is a daunting challenge with many competing interests that may affect study results. Participants did not have to report high-risk behaviors to enroll in the INSPIRE project; they were required to be sexually active (past 3 months) and to have injected (safely or not) in the past year. To try to reach participants who might be more amenable to behavior change, an original study goal was to have 50% of the participants be newly diagnosed with HIV infection (which we loosely defined as being diagnosed with HIV in the past 3 years). We had hypothesized that these newly diagnosed IDUs would be riskier and less likely to have benefited from previous prevention efforts at the 4 sites. The final tally for "newly"

diagnosed participants was less than 20%, however, and our study sample had known about their HIV status for 9 years on average. Partly, this reflects the fact that IDUs are becoming HIV-infected at a much lower rate compared with earlier in the epidemic. It may also reflect the challenge of getting people into prevention services while they are still trying to incorporate the fact of being HIV-positive into various aspects of their lives.⁵¹ It is important to note, however, that despite recruiting a lower risk sample, we did significantly reduce risk behaviors in both groups.

Finally, 2 characteristics of the PMI deserve specific mention; namely, the use of complex hierarchic messages to deliver risk information and trying to tap into the altruism of participants to protect their partners. Rather than having a simple intervention message regarding risk, which was not found to be realistic by participants during piloting, the study team chose to develop risk hierarchies for sex and injection behaviors. Participants were provided risk hierarchies in the group sessions and encouraged to alter their behavior in a safer direction, no matter where they were initially, and a personalized plan was then developed in the individual session. Having broad risk reduction goals that included multiple hierarchic risk reduction messages (rather than focusing on a single high-risk behavior) may have interfered with the intervention group in reducing their risk more than that of the control group,⁵² and has been a concern in another intervention trial for HIV-positive persons.⁴⁷ In addition, tapping into participant altruism to protect others (eg, our message about power to protect) may not change behavior in the intended manner,⁴⁷ even when paired with more traditional messages about self-protection. Having HIV-positive persons focus on protecting others and their communities may recall past antisocial behaviors, emphasize the difference between infected and uninfected persons, and create negative mood states that interfered with adopting safer behaviors.⁴⁷ A recent study of messages provided to HIV-positive persons (not all IDUs) in clinics found that loss-framed messages (eg, this is how risk behavior might hurt you) reduced risk behaviors significantly more than gain-framed messages (eg, these are the benefits of not being risky).⁵³ More research is needed as to whether simpler or more negatively framed messages may be more effective for HIV-positive IDUs. We cannot unequivocally determine the effects of our messages because both groups changed risk behaviors.

This study had some additional limitations worth noting. First, the study sample was recruited through diverse strategies but was not representative of all HIV-positive IDUs, or even all HIV-positive IDUs in the cities in this study. Although overall attrition was low for this IDU sample (attrition between baseline and randomization was just 23%, and attrition from the 2 conditions was <20%), any attrition limits the generalizability of the study. Finally, the use of incentives to increase attendance at intervention sessions and assessments also limits the generalizability of our study, as does the use of long assessments to measure risk behavior and hypothesized correlates of behavior change.

Despite the fact that the number of interventions targeting HIV-positive persons is great enough to allow for a meta-analysis,¹⁵ none of the interventions for HIV-

positive persons have been found to be effective for HIV-positive IDUs in the community. The present intervention suggests that further research is needed on how best to reach and provide prevention services to HIV-positive IDUs. Partly as a result of the federal partners brought together to fund this study, the INSPIRE study group tried to address 4 broad outcomes in a relatively brief intervention (particularly brief when considering time available for each primary outcome). Future interventions might benefit from a more targeted approach to outcomes, a simpler intervention message, more individualized time, a less burdensome assessment, and providing the intervention in a health care setting. The biggest challenge for interpreting our results is that both interventions decreased sexual and drug risk. Some of the commonalities in these 2 interventions should be included in future research trying to untangle the competing explanations for our findings. Commonalities in our 2 interventions included use of knowledgeable (and often HIV-positive) peers as facilitators, emphasizing among all levels of staff the importance of providing respect and support for this particularly marginalized group, and use of groups in which participants were able to interact with other HIV-positive people. No one observing an INSPIRE graduation session would doubt the power of positive attention and support for such a marginalized and stigmatized group of people. Although the intervention and control conditions produced similar outcomes, there are a number of lessons to be learned from the INSPIRE trial that can help future intervention researchers to design more effective health promotion and disease prevention interventions for this population.

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