

Interventions for Seropositive Injectors—Research and Evaluation

An Integrated Behavioral Intervention With HIV-Positive Injection Drug Users to Address Medical Care, Adherence, and Risk Reduction

David W. Purcell, JD, PhD,* Lisa R. Metsch, PhD,† Mary Latka, PhD,‡
Scott Santibanez, MD, MPHTM,* Cynthia A. Gómez, PhD,§ Lois Eldred, MPH, DrPH,|| and
Carl A. Latkin, PhD¶ for the INSPIRE Study Group

Background: Behavioral interventions to address the complex medical and HIV risk reduction needs of HIV-seropositive (HIV-positive) injection drug users (IDUs) are urgently needed. We describe the development of Interventions for Seropositive Injectors—Research and Evaluation (INSPIRE), a randomized controlled trial of an integrated intervention for HIV-positive IDUs, and the characteristics of the baseline sample.

Methods: HIV-positive IDUs were recruited from community settings in 4 US cities. After completing a baseline assessment, participants who attended the first session were randomly assigned to (1) a 10-session peer mentoring intervention designed to improve utilization of HIV care, to improve adherence to HIV medications, and to reduce sexual and injection risk or (2) an 8-session videotape control. Periodic follow-up for 12 months is ongoing.

Results: A total of 1161 HIV-positive IDUs completed the baseline assessment, and 966 (83%) were randomized. Retention rates are greater than 80% for all follow-up periods. Approximately 79% of baseline participants reported a recent medical visit, 49% were taking highly active antiretroviral therapy, and 19% had an undetectable viral load. Use of injection and noninjection substances was prevalent, and sexual and injection risks were each reported by more than 25% of participants.

Conclusion: There is a need for an integrated intervention for HIV-positive IDUs, and these data show the acceptability of such an approach.

From the *Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, GA; †Department of Epidemiology and Public Health, University of Miami, Miami, FL; ‡New York Academy of Medicine University, New York City, NY; §Center for AIDS Prevention Studies, University of California at San Francisco, San Francisco, CA; ||Health Resources and Services Administration, Rockville, MD; and ¶Department of Health Policy and Management, Johns Hopkins University, Baltimore, MD, and the INSPIRE Study Group.

Reprints: David W. Purcell, Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E-37, Atlanta, GA 30333 (e-mail: dpurcell@cdc.gov).

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At the end of 2000, the Centers for Disease Control and Prevention (CDC) estimated that 850,000 to 950,000 Americans were living with HIV infection and that approximately 40,000 new infections continue to occur every year.¹ These data emphasize the need for continued efforts in preventing new infections as well as new strategies to provide medical and prevention services to HIV-seropositive (HIV-positive) persons. Recent CDC initiatives have emphasized the need to develop science-based prevention interventions specifically designed for HIV-positive persons.^{1,2} These CDC initiatives are in response to a growing body of literature showing that although many people decrease their risk behaviors after learning that they are HIV-positive through HIV counseling and testing,^{3–5} a considerable proportion continue to engage in or relapse to unsafe sexual and injection risk behaviors.^{6–8}

HIV-positive injection drug users (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. IDUs represented 36% of the women living with AIDS in the United States in 2002 and 23% of the men (31% when gay/bisexual IDUs are included).⁹ Recent studies have shown strong independent effects of unprotected sexual behaviors as risk factors for HIV seroconversion among IDUs.^{10,11} This is particularly important because prevention efforts directed toward IDUs generally have shown greater success in reducing injection risk behavior than sexual risk behavior.^{12–14}

As a group, HIV-positive IDUs are at risk for a myriad of health and psychosocial problems. Given the high rates of substance abuse, mental illness, and marginal employment and housing among HIV-positive IDUs, they may be particularly challenged in their efforts to access HIV-related medical care,

adhere to HIV medications, and reduce sexual and injection risk behaviors. Studies have consistently shown that they are less likely to receive HIV primary care and highly active antiretroviral therapy (HAART),¹⁵⁻¹⁷ are more likely to lack insurance,¹⁸ and are more likely to be hospitalized than non-IDUs.¹⁹ For those HIV-positive IDUs who do initiate HAART, some recent studies have shown that injection drug use is associated with decreased levels of adherence and attendance at HIV primary care clinics,^{20,21} although other studies have shown no association between injection drug use and adherence after adjusting for confounding variables.^{22,23}

To date, there has been only 1 behavioral intervention trial with HIV-positive IDUs, and this study focused on reducing risk behavior of drug users entering methadone treatment.²⁴ There are no effective published interventions designed to address medical care, adherence to HIV medications, and behavioral risk reduction among HIV-positive IDUs in an integrated manner. Within this context, in 1999, the CDC; Health Resources and Services Administration (HRSA); and research teams in Baltimore, Miami, New York, and San Francisco developed and implemented Interventions for Seropositive Injectors—Research and Evaluation (INSPIRE). INSPIRE was designed to test the efficacy of an integrated behavioral intervention to (1) increase utilization of HIV medical care, (2) increase adherence to HIV medications, (3) reduce injection risk behavior, and (4) reduce sexual risk behavior. For the latter 2 outcomes, we were particularly interested in decreasing risk behavior with HIV-negative or unknown serostatus injection or sex partners.

This report describes the methods used to develop and test INSPIRE within a randomized controlled trial (RCT). We

provide data about our ability to recruit, randomize, intervene with, and follow a large diverse group of HIV-positive IDUs. In addition, we provide baseline data for the medical and prevention outcomes that demonstrate the need for an integrated intervention. Because follow-up is ongoing, the final outcomes of the RCT are pending.

METHODS

We were particularly interested in reducing sexual risk because of its importance in current transmission of HIV among IDUs. Thus, in determining the statistical power needed for the intervention trial, we used sexual risk data from previous studies of primarily heterosexual HIV-positive IDUs, which indicated the need for 800 participants at the 12-month follow-up to provide 82% power to detect a 30% reduction in sexual risk behavior between the 2 arms. Specifically, we were looking for a 30% reduction in unprotected vaginal or anal sex with HIV-negative or unknown serostatus partners. The intervention was extensively piloted in all 4 cities before implementation, and we received additional input from local community advisory groups of HIV-positive IDUs and their advocates. Finally, all activities were approved by institutional review boards at each collaborating institution and the CDC. Figure 1 illustrates the overall design of the RCT and the number of participants achieved or projected for each stage of the study.

Recruitment and Screening

Participants were recruited using active outreach and passive strategies (posters and flyers) in a variety of community venues such as AIDS service organizations, HIV medical clinics, methadone clinics, needle exchange programs, and

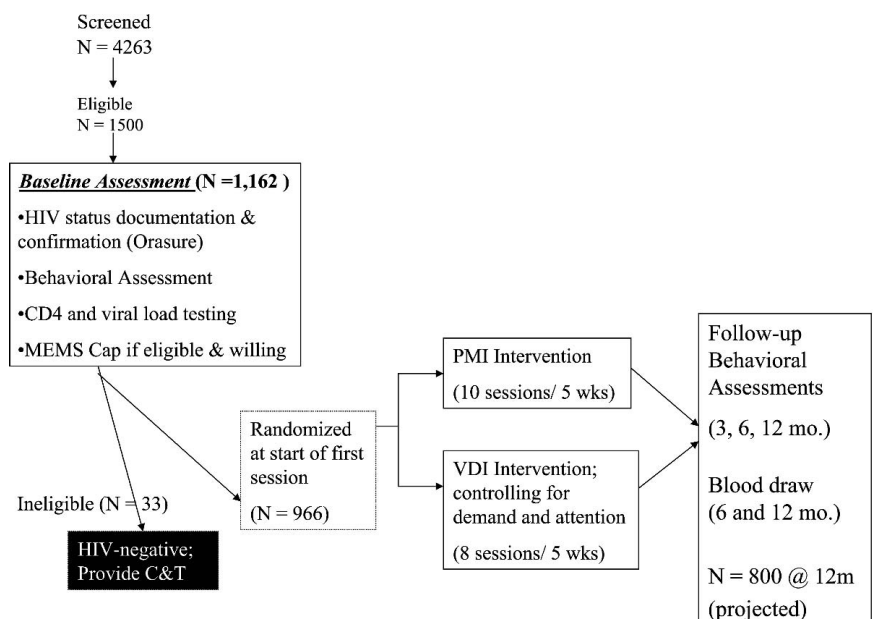


FIGURE 1. Interventions for Seropositive Injectors—Research and Evaluation participant flow diagram. C&T indicates counseling and testing; PMI, peer mentoring intervention; VDI, video discussion intervention.

other programs serving HIV-positive IDUs as well as street-based settings where drugs users can be found. Although there were slight variations across sites, the recruiting cards and flyers generally advertised the study as follows: "INSPIRE, a research study for HIV-positive men and women who use drugs. Come participate in an exciting program to help you improve your health and the health of your community. You will be compensated for your time and travel expenses. Call our toll-free phone number so you can participate!"

HIV-positive drug users who were interested in the study were provided information about the study at the recruiting location, or they could call a toll-free telephone number for information. To eliminate the need for potential participants to disclose their HIV status in outreach venues, potential participants were told, "If this card does not apply to you, please give it to someone you know." This statement was also printed on the recruitment cards and posters. As a result, some potential participants were reached through referrals made by friends who passed the card on to others.

Potential participants were screened at the recruitment venue or by telephone. During screening, they received information about the purpose of the study and the activities that were involved. To be eligible for the study, potential participants had to (1) be at least 18 years old, (2) report injection drug use in the past year, (3) report sex with at least 1 opposite-sex partner in the past 3 months, (4) self-identify as HIV-positive, (5) be willing to have their HIV serostatus confirmed through an HIV test of oral fluids, (6) agree to a blood draw for CD4 and viral load testing, (7) not be currently enrolled in an intervention study conducted by one of the Principal Investigators or have been enrolled in the pilot study, (8) live within the study area and be willing to provide contact information, (9) be able to communicate in a group in English (although assessment could occur in Spanish), and (10) indicate availability to attend the first intervention session. Based on formative data as well as feedback from local community advisory boards, which reported that heterosexual IDUs have different needs regarding sexual risk reduction than IDUs who are men who have sex with other men (MSM) only, the intervention was designed for persons who had at least 1 opposite-sex sexual partner in the past 3 months. Thus, MSM who also had recent female sexual partners were eligible, whereas those who had only male partners were not. Similarly, women who only had female sexual partners were not eligible. Eligible participants were invited to join the study and scheduled for the first study appointment. Eligible participants who did not attend a baseline appointment within 60 days had to restart the eligibility process.

Baseline Appointment

At the baseline appointment, we collected biologic and behavioral data to obtain preintervention measures of behavior. After consent and collection of detailed locator informa-

tion, participants provided an oral fluid sample for confirmatory HIV antibody testing (OraSure; OraSure Technologies, Bethlehem, PA). Oral specimens were sent to local laboratories and were not available for 1 to 2 weeks. However, if participants had documentation of their HIV status, they continued with their baseline appointment with the assumption that the OraSure test would confirm that they were HIV-positive. Eligible participants without HIV documentation completed their baseline appointment after they were confirmed to be HIV-positive by the OraSure test. A small number of participants ($n = 33$) who completed the baseline procedures were excluded from the study because their OraSure results did not indicate the presence of HIV antibodies and seropositivity could not be confirmed through repeat testing or other documentation. These persons were provided standard HIV posttest counseling and referrals.

After oral specimen collection, 3 tubes of blood were collected and sent to the CDC laboratories for CD4 count and viral load testing and for storage for future testing and research. In all cases, if blood could be drawn, it was drawn before the first intervention session occurred. After testing, results of CD4 count and viral load testing were sent back to sites. Participants could select 1 of 3 ways to receive their results: (1) directly from project staff only, (2) directly from project staff and have results sent to care providers, or (3) directly from care providers only. If the participants met with project staff to receive results, a structured script was followed and participants were advised to discuss the results with their provider. Most participants chose to send their results only to their provider and thus not to receive results from INSPIRE staff.

After the blood draw, participants were administered an audio computer-assisted self-interview (A-CASI)²⁵ for baseline self-reported measures. Before the assessment, participants were provided 2 calendars to orient them to the recall periods and a sheet to help them calculate the number of times they had engaged in various behaviors (eg, "once a week equals 12 times in the past 3 months"). During a training session, participants were oriented to the computer and answered a series of practice questions. Staff also assisted during the first section of the assessment, which focused on current HIV medications. Thereafter, the participants worked on the computer privately but could contact staff at any time for questions. Privacy was important, because this method yields more reliable reporting for stigmatized sex and injection behaviors.²⁶ Two short mandatory breaks were programmed into the A-CASI assessment, which required, on average, 87 minutes to complete (SD = 33 minutes).

Participants who were taking HIV medications were asked to bring their medication bottles to the baseline visit. At 3 of the 4 sites, participants who were taking HIV medications and were not currently using an adherence aid (eg, pill box) were asked to use a medication event monitoring system

(MEMS) cap²⁷ on 1 of their HIV medications (chosen by algorithm) to provide an additional measure of adherence. MEMS caps are devices that replace the top of a bottle of medications, and they record each opening of the bottle. MEMS caps are considered an objective measure of adherence, because each opening is assumed to correspond with taking the medication. Participants who were eligible for a MEMS cap were encouraged to use one, but if they elected not to, they remained eligible for the study. One site (San Francisco) chose not to offer MEMS caps to its participants because of the large number of studies using MEMS caps in the area.

Finally, a photograph was taken, and participants were given a project identification (ID) card with their picture. Having a picture helped sites to identify participants during follow-up visits, and participants often were proud of their project ID card.

First Intervention Session and Randomization

During the baseline appointment, participants were given a date to return for the first session for randomization into 1 of the 2 intervention conditions. Up to 30 participants who had completed the baseline appointment were invited to attend each randomization, and those who attended constituted 1 cohort. Participants were randomized in small blocks by gender using an algorithm that assigned participants to 1 of the 2 intervention arms (either the peer mentoring intervention [PMI] or the video discussion intervention [VDI]). At each site, the randomization was conducted by 1 designated staff member and the program was not accessible to other staff. If participants missed the randomization session, they could be rescheduled for a later randomization session in some cases. A participant whose baseline assessment was more than 90 days old had to be screened again and attend another baseline visit before being assigned to a cohort. If a participant missed more than 2 randomization sessions or more than 2 baseline assessments, he or she was ineligible for the trial.

Integrated Intervention: Peer Mentoring Intervention

The PMI drew on a novel combination of sociological and psychological literature and was based on the concepts of empowerment^{28,29} and peer leadership or advocacy,³⁰ with exercises and activities grounded in social learning theory (SLT)³¹; social identity theory³²; and the information, motivation, and behavioral skills (IMB) model.³³ The purpose of the PMI, as presented to participants, was to help them learn and try out a new social role. Learning to be peer mentors would help them to better protect themselves and their communities from HIV and other infections. The notion of peer mentoring was introduced in the first PMI session and included across all sessions. This concept was developed from research showing that people who take on a new prosocial, helping role are better able to change behaviors and more easily master newly ac-

quired skills such as condom negotiation and risk reduction.^{28,29,32} Formative work at all 4 sites indicated that many HIV-positive IDUs were seeking such a role—they wanted to help others avoid HIV and help themselves. The peer mentoring framework also helped to decrease potential resistance to discussing familiar or uncomfortable topics (eg, “You may know how to put on a condom, but your peers might not, so let’s review the steps and practice on this model”) and to circumvent an optimistic bias³⁴ (eg, “Other people may not know how to reduce their risk, but I know how to”).

Other important elements incorporated across PMI sessions (10 sessions over 5 weeks) included (1) culturally appropriate videotapes with characters similar to the participants to model prosocial behavior and peer mentoring; (2) interactive discussions to gauge the existing knowledge and beliefs of the group, provide information, set new norms, and increase motivation; (3) exercises focused on injection and sexual risk behaviors; (4) activities such as skills building, role plays, and practice; (5) between-group homework activities related to peer mentoring or other skills with reports back and discussion at the next session, and (6) a resource table with community contacts and risk reduction information and tools (eg, condoms).

The PMI content addressed utilization of HIV primary care, adherence to HIV medications, and sex and injection risk behavior associated with HIV transmission. Seven of the sessions were mixed-gender group sessions led by a male facilitator and a female facilitator, 2 were individual sessions led by the matched-gender facilitator, and 1 consisted of a peer volunteer activity (PVA), as described below. We chose a mix of group and individual sessions because we wanted to provide support, modeling, and motivation found in group interventions, but we also wanted to tailor for participants’ unique challenges related to gender, drug of choice, medical status, and sexual behavior. Two 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. The final group session focused on review and reinforcement of motivation and skills for behavior change, and it ended with a graduation ceremony where participants received certificates. The goals of reducing perceived stigma and increasing disclosure of HIV status and drug use were addressed through interactive session exercises, by providing participants an opportunity to disclose their status while helping their peers to obtain medical care, and by developing a social role that encouraged participants to be health advocates.

In session 9, participants were scheduled for a peer volunteer activity during which they went to a local service organization for 2 to 4 hours to observe, participate in, and practice their peer mentoring skills. Participants were prepared for this activity through previous group and individual sessions as well as through homework activities that usually required peer interaction. The purpose of this activity was to have participants

adopt a new and empowering social role, one in which they were aligned with the providers at an agency rather than being a service receiver (a more familiar role). Participants selected a PVA site from a list developed at each site. Agencies were screened to ensure that each PVA site was a place where participants could talk about HIV and share their stories or interact with others like them (HIV-positive persons or drug users). Participants were encouraged to use their peer mentoring skills and share the HIV-related knowledge they were learning in the PMI.

Control Condition: Video Discussion Intervention

Participants in the VDI took part in 8 sessions over 5 weeks. The VDI condition controlled for attention and experimental demand, and it provided 1 session of basic HIV prevention information. Although the number of sessions in the VDI was 2 less than that of the PMI, the 8 VDI groups represented the same amount of group time (16 hours) as the PMI. Session 1 provided a standard-of-care intervention by using a didactic format to provide information on all key intervention topics (medical care, adherence, sex risk, and injection risk). 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."

The format for each VDI session involved a brief check-in with participants and the viewing of videotape(s) on topics that were relevant and interesting to the participants' lives (45–80 minutes), followed by facilitated discussion. Videotapes were selected after extensive screening and piloting. Topics included prejudice and discrimination, getting a job, Red Cross safety tips (with an additional segment developed by 1 of the research sites on drug overdose prevention), substance use in families, parental disclosure of HIV status to children, and prison experiences. After the first session, the facilitators were trained to steer the discussions to minimize the focus on our main intervention topics (HIV medical care, adherence, and HIV risk reduction). As in the PMI, however, community resources and risk reduction information and tools (eg, condoms) were available at every VDI session.

Facilitator Training and Quality Assurance

Intervention facilitators had prior professional experience in working with the target population or in conducting HIV prevention activities, and some were HIV-positive, former IDUs, or both. Advanced education was not required. Facilitators were trained at a 3-day national meeting, and they used detailed manuals to deliver the PMI and VDI. During the study, intervention facilitators were supervised locally by senior research staff. During the 28 months that the intervention was delivered, facilitators took part in monthly cross-site con-

ference calls with CDC staff to discuss challenges. As appropriate, these issues were addressed by local supervisors and a cross-site intervention committee composed of senior research staff and scientists who developed the intervention.

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 cohort condition at every site was randomly selected. This schedule was not revealed to the facilitators. These selected tapes were reviewed and rated by 2 senior project researchers. Tapes were rated for adherence to the intervention manual, and any problems that were identified were reported back to site supervisors to incorporate into facilitator supervision.

Follow-Up

Follow-up assessments were scheduled 3, 6, and 12 months after the last intervention session. Window periods were established within which a participant's follow-up visit must be completed or it was considered missed, unless the participant was in the hospital or prison and could be rescheduled after release. In most cases, follow-up assessments were not allowed to occur within 90 days of each other (because of recall periods of 90 days). Behavioral assessments using A-CASI were administered at each follow-up. In addition, participants returned with their MEMS cap at each follow-up, the data were downloaded, and the cap was returned to the participant. Participants also were asked to provide blood samples at the 6- and 12-month follow-up visits, and results were provided using the procedures described for the baseline visit.

Reimbursement for Time and Effort

Monetary incentives were provided for all study activities to reimburse participants for their time and effort. Participants in both conditions received \$30 at the baseline assessment and \$35, \$45, and \$50 for the 3-, 6-, and 12-month follow-up assessments, respectively. Those who were eligible and opted to use the MEMS cap were reimbursed an additional \$5 at baseline and at each follow-up visit to which they brought their cap. Participants were reimbursed \$20 for each intervention session they attended. In addition, small nonmonetary gifts (eg, tee-shirt with the project logo, condom carrying case, journal) and refreshments were provided at each session for both conditions.

MEASURES

The A-CASI baseline and follow-up assessments consisted of items measuring the following major domains: (1) demographics; (2) HIV-related medications and adherence, health status, and use of HIV primary care; (3) sexual practices; (4) injection drug use and practices; (5) alcohol and non-injection drug use; and (6) self-efficacy, perceived norms, and other cognitive and psychosocial constructs related to the study outcomes. Participants reported about risk behavior with HIV-positive, HIV-negative, and unknown serostatus partners

separately. With this assessment, we are able to focus outcome analyses on transmission risk with HIV-negative and unknown status partners.

Regarding HIV medications, we used current US Department of Health and Human Services (DHHS) guidelines³⁵ to classify participant medication regimens as HAART or antiretroviral therapy (ART). HAART included regimens that were “strongly recommended” and “recommended as alternatives” by current guidelines, plus newer agents available through expanded-access programs and expected to be approved but not yet included in the guidelines, and second-line and salvage regimens which, although not a preferred initial regimen, could still be considered appropriate therapy at the time of this study. ART included any antiretroviral in a combination other than above.

RESULTS

First, we provide data on the implementation of the trial and follow-up assessments. We then provide an overview of characteristics of the baseline sample.

Randomized Controlled Trial

A total of 4263 persons were screened for eligibility, of whom 1500 (35.2%) satisfied screening eligibility criteria (see Fig. 1). Of these 1500 persons, 1161 (77.4%) enrolled in the study and completed a baseline assessment. We collected blood for CD4 count and viral load testing from more than 96% (1121 of 1161) of participants at baseline. Regarding differences between those baseline participants who attended the first session and were randomized (n = 966) versus those who were not randomized (n = 195), there were no differences between these 2 groups on most demographic variables or for any risk or outcome variables. There was a significant difference by race, with the percentage of baseline participants who were randomized being 87% black, 79% white, 74% Hispanic, and 84% of other races (χ^2 [3, N = 1141] = 21.68, $P < 0.001$).

Of baseline participants, 966 (83.2%) came to the first intervention session and were randomized to a condition. Paired VDI and PMI groups (70 of each) were conducted between August 2001 and December 2003. Three sites conducted 18 group pairs, and the New York site conducted 16 group pairs (fewer because of the 9/11 tragedy). The average size of a cohort was 13.8 participants, or approximately 7 participants per group.

Condition assignment is currently blinded, so we cannot yet evaluate retention by condition. Overall retention through January 2004 has been 87% at the 3-month follow-up (cohorts 1–13), 83% at 6 months (cohorts 1–10), and 86% at 12 months (cohorts 1–3), however. If the follow-up rate at 12 months continues at 86%, our final 12-month sample should be approximately 831 people, which would meet the target of 800 required by the power analysis.

Characteristics of the Baseline Sample

Demographic characteristics of INSPIRE participants who completed the baseline instrument are shown in Table 1. The sample was recruited by means of a variety of methods,

TABLE 1. Baseline Characteristics for INSPIRE Participants

	Total (N = 1161)*
City	
Baltimore	313 (27.0%)
Miami	298 (25.7%)
New York	271 (23.3%)
San Francisco	279 (24.0%)
Recruitment source	
Friend/word of mouth	305 (26.4%)
Recruitment staff	206 (17.8%)
Flyer/poster	175 (15.1%)
AIDS service organization	134 (11.6%)
Needle exchange	87 (7.5%)
Methadone maintenance program	63 (5.4%)
HIV care clinic	55 (4.8%)
Other	115 (9.9%)
Gender	
Male	700 (60.3%)
Female	426 (36.7%)
Transgender	35 (3.0%)
Race/ethnicity	
Non-Hispanic black	740 (63.7%)
Hispanic	201 (17.3%)
Non-Hispanic white	113 (9.7%)
Non-Hispanic other	87 (7.5%)
Sexual orientation	
Heterosexual	814 (70.8%)
Bisexual	211 (18.4%)
Gay, homosexual	65 (5.7%)
None of the above, not sure	59 (5.1%)
Education	
Eighth grade or less	180 (15.6%)
Some high school	328 (28.4%)
High school graduate or GED	361 (31.3%)
Some college or beyond	286 (24.7%)
Current employment	
Yes	62 (5.4%)
No	1096 (94.6%)
Personal annual income	
Less than \$5000	595 (53.2%)
\$5000–\$9999	370 (33.1%)
\$10,000–\$19,999	118 (10.5%)
\$20,000 or more	36 (3.2%)

*Number of respondents may not add up to 1161 because of missing data.

with no one method representing more than 30% of the sample. More than 60% of participants were male and black. The mean age was 42 years (SD = 6.6, range: 22–60 years). Of the 35 transgender participants, most (94%) were biologically male but had a female gender identity. Regarding sexual orientation, although more than 70% of the sample identified as heterosexual, 18% of the sample identified as bisexual and 5% each identified as gay or none of the above. Study participants reported low levels of employment and education; 33% reported being homeless in the past year, and less than 25% had education beyond high school. More than 85% reported that their annual income was less than \$10,000, indicating that a substantial number of participants had incomes below the 2000 federal poverty threshold of \$8959.³⁶

Most participants had known their HIV serostatus for many years. The mean time since HIV diagnosis was 9.1 years (SD = 5.1 years, range: 1 month to >19 years). More than three quarters of participants (79%) reported a primary health care visit for their HIV in the past 6 months. Approximately one quarter of participants (24%) reported having no medical insurance or medical coverage, including Medicare, Medicaid, and other publicly funded programs. Nearly all participants who visited a doctor for their HIV in the past 6 months also reported having a CD4 count or viral load test during that visit. The mean CD4 count from the baseline laboratory data was 380 (SD = 287, median = 325) cells/mm³, and 19% (211 of 1113) of participants had an undetectable viral load.

There was variability in the use of and adherence to HIV medications. Five-hundred sixty (49%) participants reported that they were currently taking a HAART regimen recommended by DHHS guidelines, and 501 (44%) reported that they were not taking any HIV medication. The remaining 76 (6.7%) reported other combinations of ART. Of the people not taking medications, 106 (21%) fit the DHHS guidelines criterion of a CD4 count <200 cells/mm³ for HAART. Self-reported adherence data indicate that 25% of those on HAART missed at least 1 dose during the previous day.

Regarding substance use, 84% of participants reported injecting drugs in the 90 days before baseline. Of the people who injected, the most commonly injected drugs were heroin (59.1%), speedball (heroin and cocaine mixed together, 50.7%), cocaine or crack (31.6%), and amphetamines (12.2%). Use of non-injection drugs was common, with 73% reporting use of such substances in the 90 days before the baseline assessment. Of those who used non-injection drugs, the most commonly used substances were crack (66.3%), heroin (63.1%), cocaine (55.4%), and marijuana (47.5%). Inpatient drug treatment was reported by 35% of participants at least once in the past 6 months, and 32% of participants reported current enrollment in a methadone maintenance treatment program.

Regarding HIV risk behaviors, 315 (28%) participants reported sexual transmission risk behavior (eg, unprotected

vaginal or anal sex with an HIV-negative or unknown status partner in the past 3 months). Sexual risk with HIV-positive sexual partners was reported by 332 (29%) of participants. Sex with men and women was reported by 165 (14%) of participants. Regarding HIV injection risk, 12% of participants (n = 137) reported lending needles after use, and 27% (n = 302) reported sharing drug paraphernalia (eg, cottons, cookers, rinse water) with an HIV-negative or unknown status partner in the past 3 months. Sharing with HIV-positive partners was more common, with 33% of participants lending a needle and 65% of participants sharing paraphernalia with HIV-positive drug-using partners.

DISCUSSION

INSPIRE represents the first efficacy trial of an integrated intervention to address the medical care, adherence, and behavioral risk needs of HIV-positive IDUs. This more holistic approach is consistent with recent initiatives suggesting the need to strengthen the connection between prevention and care.³⁷ The integrated nature of the PMI is a strength because it encourages participants to address several major health and behavioral needs as a whole in a supportive environment. This integration also posed a methodologic challenge, however, because incorporating multiple behavioral targets might dilute the intervention effects on any single outcome. Although recent research indicates that HIV-positive IDUs in medical care³⁸ and those who are adherent to their HIV medications^{39,40} may be less likely to engage in sexual risk, addressing medical care, adherence, and risk behavior in a single intervention required more sessions and less time for each topic.

The INSPIRE baseline data collected from a diverse sample in 4 cities indicated that a large number of HIV-positive IDUs engage in high-risk injection and sexual behavior with HIV-negative or unknown status partners. Moreover, many participants were not receiving optimal medical care for their HIV, which supports the inclusion of HIV medical care as a focus of this intervention. Our finding of 49% of participants receiving HAART is comparable to findings of other recent reports showing 40%, 51%, and 57% of participants, respectively, receiving a HAART regimen recommended at the time of the study.^{41–43} Others report HAART use among IDUs as high as 78% when used in combination with methadone maintenance, suggesting that high levels of coverage can be achieved.⁴⁴

The diversity and size of the sample are 2 of the major strengths of the INSPIRE study. Participants were recruited from a variety of community settings and included significant numbers of black and Latino men and women. The size of the sample makes it possible in future analyses to evaluate the influence of racial/ethnic and other subgroup differences that could not be studied in a smaller sample. The detailed information collected about specific sexual practices is another strength. INSPIRE is one of the few studies that measured sex-

ual practices with HIV-positive, HIV-negative, and status unknown partners in a way that makes it possible to examine the influence of relationship status and partner serostatus.

Regarding limitations, the trial was not designed to recruit a representative sample of HIV-positive IDUs. For example, IDUs who were exclusively MSM were excluded partially because of anticipated challenges of group process among MSM and heterosexual IDUs. In addition, because both intervention conditions included group sessions, participants had to be willing to disclose their serostatus to unfamiliar persons. Therefore, study findings may not be generalizable beyond the population of HIV-positive IDUs who are inclined to join an intensive study such as this. Although retention thus far has been good for follow-up assessments, generalizability is reduced by having relatively strict eligibility criteria, 17% attrition from baseline to attendance at the first intervention session, 13% to 17% attrition from the first session to follow-ups, and the use of incentives to maximize intervention participation.

Undertaking a rigorous RCT of a complex intervention like INSPIRE is costly. Nevertheless, there is potential reward if the intervention is efficacious so that it can be disseminated to meet the urgent need for evidence-based interventions among HIV-positive persons, particularly among HIV-positive IDUs. The baseline data illustrate the great need among this population for services related to HIV primary care, adherence, and HIV risk reduction. It also is feasible for CBOs to implement INSPIRE. It can be staffed by well-trained nonprofessional staff, and its program costs for implementation of sessions seem reasonable. Data from a prospective cost analysis of program and participant costs for INSPIRE indicate that this intervention is likely to be cost-effective if HIV sexual risk reduction goals are met in the intervention group.⁴⁵ If INSPIRE is efficacious, we will make efforts to disseminate it to agencies that can use it to help HIV-positive IDUs and their communities improve their overall health and reduce the burden of disease.

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