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THE STAYING SAFE INTERVENTION: TRAINING PEOPLE WHO INJECT DRUGS IN STRATEGIES TO AVOID INJECTION-RELATED HCV AND HIV INFECTION

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Abstract

This pilot study explores the feasibility and preliminary efficacy of the Staying Safe Intervention, an innovative, strengths-based program to facilitate prevention of infection with the human immunodeficiency virus and with the hepatitis C virus among people who inject drugs (PWID). The authors explored changes in the intervention's two primary endpoints: (a) frequency and amount of drug intake, and (b) frequency of risky injection practices. We also explored changes in hypothesized mediators of intervention efficacy: planning skills, motivation/self-efficacy to inject safely, skills to avoid PWID-associated stigma, social support, drug-related withdrawal symptoms, and injection network size and risk norms. A 1-week, five-session intervention (10 hours total) was evaluated using a pre- versus 3-month posttest design. Fifty-one participants completed pre-

and posttest assessments. Participants reported significant reductions in drug intake and injection-related risk behavior. Participants also reported significant increases in planning skills, motivation/self-efficacy, and stigma management strategies, while reducing their exposure to drug withdrawal episodes and risky injection networks.

Human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infection among people who inject drugs (PWID) are significant and persistent public health challenges. The Centers for Disease Control and Prevention (CDC) estimate that in the United States 9% of new HIV infections can be attributed to injection drug use (Prejean et al., 2011), and 18% of PWID are HIV positive. In contrast, PWID make up the majority of persons with HCV infection in the United States, and HCV prevalence among PWID has been estimated at 70%–77% (Hagan, Pouget, Des Jarlais, & Lelutiu-Weinberger, 2008). Although syringe exchange programs (SEPs), opioid substitution therapy (OST), and other harm reduction programs have been shown to reduce parenteral HIV transmission among PWID in locations where they have been implemented to scale, their effect on HCV transmission has been less conclusive and of smaller magnitude. A number of social/behavioral interventions have reduced syringe sharing, but they have had less success in preventing the sharing of other injection equipment, such as cookers, cotton filters, and water, behaviors that have been shown to efficiently transmit HCV (Doerrbecker et al., 2013; Hagan, 2011; Hagan et al., 2001; Mateu-Gelabert et al., 2007). In recent research (Friedman, Mateu-Gelabert, Sandoval, Hagan, & Des Jarlais, 2008; Friedman, Mateu-Gelabert, Sandoval, & Meylakhs, 2013; Friedman, Sandoval, Mateu-Gelabert, Meylakhs, & Des Jarlais, 2011; Mateu-Gelabert, Sandoval, Meylakhs, Wendel, & Friedman, 2010; Vazan, Mateu-Gelabert, Cleland, Sandoval, & Friedman, 2012), our team has sought to understand factors underlying persistent injection risk behavior among the PWID population, as described in this article.

In 2005 we conducted a study, entitled *Staying Safe*, to examine the behaviors and strategies of individuals who had injected drugs for long periods of time (8–15 years) but had *not* contracted HIV or HCV. The study was based on the assumption that identifying the social and structural resources these individuals either accessed or created, along with the specific protective behaviors and routines they developed, would provide valuable guidance for future HIV and HCV prevention programs for PWID. The *Staying Safe* study utilized a “positive-deviance control-case life history” approach (Friedman et al., 2008) to examine the life histories, social and structural contexts, and pragmatic strategies of these HIV/HCV-negative (i.e., “doubly uninfected”) PWID as compared to their HIV- and/or HCV-infected counterparts. We found support for many of the standard approaches to HIV and HCV risk reduction, such as avoiding injecting with used syringes or other injection equipment. Furthermore, we found that doubly uninfected PWID aimed to achieve “symbiotic goals”—that is, goals not directly focused on disease prevention but that nonetheless facilitate disease prevention. For example, these symbiotic goals included strategies such as planning ahead to have access to sterile injection equipment and avoid unsafe injection locations; managing drug intake to better control drug dependence, thereby avoiding major pitfalls such as job loss, engaging in crime, or burdening partners or family members; and avoiding drug withdrawal states that tend to undermine personal norms and social prohibitions against

syringe sharing. Furthermore, we found social and situational factors to be critical in protecting against injection risk. Specifically, maintaining social support from nonusers played an important role in reducing risk, as did minimizing the size of one's injection network (Friedman et al., 2011). Highlighting the important role that macrolevel sociostructural factors play in shaping risk behavior of PWID (Rhodes, 2009), we also found that changes in local contextual factors, such as decreased availability of sterile syringes and increased policing activity, can promote risky injection behavior (Cooper, Moore, Gruskin, & Krieger, 2005; Des Jarlais, 2000; Mateu-Gelabert et al., 2010). These findings suggest that preventing HIV and HCV among PWID over the long term will be strengthened by a multilayered approach that addresses proximate, individual-level risk behaviors and symbiotic goals as well as “upstream” risk factors, including social networks and larger structural/environmental contexts.

THE STAYING SAFE INTERVENTION

Building on these findings, we developed a pilot social/behavioral intervention for PWID, the Staying Safe Intervention, which is directly grounded in lessons learned from injectors who avoided HIV and HCV infection over long periods of time. The Staying Safe Intervention seeks to reduce injection risk by intervening upstream in the causal chain of risk behaviors by modeling, training in, and motivating the use of strategies and practices of long-term risk avoidance. The intervention's overarching theoretical framework is Ecosocial theory (Krieger, 1994, 2001), which posits that disease risk is conferred through interactions between persons and their social environment. The Staying Safe Intervention is also informed by the Symbiotic Model of Risk Reduction (Friedman et al., 2011), which emphasizes that implementing and attaining certain goals not directly focused on disease prevention (e.g., maintaining social relations, maintaining housing) can have a “symbiotic effect” on disease prevention by reducing transmission risk. Lastly, the Staying Safe Intervention's conceptualization of the behavior change process is grounded in Social Action Theory (SAT; Ewart, 1991), an integrative social-cognitive model that identifies and targets specific individual and social processes to, in this case, reduce upstream determinants of risk and encourage injection risk-related health-protective behaviors. In SAT, health habits are framed as an organized system comprising routinized sequences of actions, consequences, and reactions that lead to predictable outcomes. These routines are typically socially interdependent—that is, interlinked with the behavior of others. To encourage behavior change, SAT seeks to enhance both the social interaction processes that drive or maintain upstream determinants of health (e.g., skills to maintain social relationships) and the individual determinants of health-related behavior, such as risk-reduction knowledge, motivation/self-efficacy for behavior change, and behavioral skills (e.g., planning). A summary of the Staying Safe Intervention's theoretical model and targeted outcomes is presented in Figure 1. The intervention sessions are summarized in Table 1. (The Staying Safe Intervention manual is available from the first author.)

The primary aim of this exploratory pilot study was to provide preliminary evidence of the feasibility and efficacy of the Staying Safe Intervention (five 2-hour sessions), a strengths-based social/behavioral intervention conducted with small groups of PWID that is designed to facilitate long-term prevention of HIV and HCV. First, we explored changes in the

intervention's two primary endpoints: (a) the frequency and amount of drug intake, and (b) the frequency of risky injection practices. Second, we explored potential changes in hypothesized mediators of intervention efficacy, namely, planning skills, motivation/self-efficacy to engage in safe injection practices (e.g., not sharing equipment with injection partners), skills to avoid PWID-associated stigma, social support, drug-related withdrawal symptoms, and injection network size and risk norms. Importantly, the intervention strives not simply to provide injectors' with basic risk-reduction knowledge, but also to enhance injectors' ability to apply this knowledge in real-world contexts.

METHODS

STUDY DESIGN

Because the Staying Safe Intervention was a newly developed, not yet tested intervention, an early-stage study utilizing a pre- versus 3-month posttest trial design was conducted to determine whether the intervention was feasible, acceptable to participants, and showed preliminary evidence of efficacy. Future research will evaluate this intervention with a larger sample in a randomized, controlled trial.

Snowball sampling of participants began with eight participants directly recruited from two sources: an SEP that provides syringe exchange, outreach, mobile health services, case management, and peer support groups to PWID; and a large research study of acute HCV infection among high-risk street-recruited injectors. Both of these recruitment sites are located in the Lower East Side neighborhood of Manhattan, an area with a high HCV prevalence among PWID (Diaz et al., 2001). These eight participants then recruited 60 eligible peers.

Eligibility criteria for participation in the study included being age 18 years or older, injecting drugs for at least a year, and showing evidence of visible track marks to confirm status as an injector. Participants were compensated \$15 for completing the pretest assessment, \$30 for completing the postintervention assessment, and \$25 for each intervention session attended. Project activities were approved by the Institutional Review Board at the National Development and Research Institutes, Inc., and by the collaborating SEP.

ASSESSMENT AND INTERVENTION PROCEDURES

Participants first completed a structured, pretest assessment that measured sociodemographic characteristics, sexual and drug use behaviors, drug use/injection networks, social support, and external and internal norms. The 45- to 60-minute computer-assisted, interviewer-administered assessment was conducted in a confidential setting at the study field site using the Questionnaire Development Systems software program (QDS; Nova Research Company, Bethesda, MD).

All participants were invited to attend the Staying Safe Intervention program, which consists of five 2-hour small-group (10–12 individuals) sessions guided by a structured manual. Intervention sessions were led by a professional group facilitator at the study field site. The first intervention session was conducted approximately 2 weeks after the pretest assessment,

with the subsequent four sessions scheduled on consecutive days thereafter. Seventy-five percent (51/68) of the participants completed the posttest assessment. Reasons for losses to follow-up included traveling outside New York State and incarceration.

ASSESSMENT MEASURES

All assessment instruments listed here, except for the measure of injection risk behavior, were developed by our research team in a prior study. The psychometric properties of these newly developed scales are described in Vazan et al. (2012).

Participant Sociodemographics—Gender, age, race/ethnicity, education level, age of first injection, and housing status were assessed at pretest. All other constructs (listed here) were assessed at pretest and 3 months postintervention in reference to the 3-month period prior to the assessment. Unless otherwise noted, responses were assessed using a 5-point Likert-type scale anchored by 0 = *Never* and 4 = *Very Often*.

Mediating Factors: Individual Determinants of Risk—Planning Ability to avoid injection-related risk was assessed using a seven-item instrument, (Cronbach's alpha = .82), which included items on (a) planning to avoid unaffordable drug intake; (b) planning to avoid drug withdrawal; (c) drug use interfering with responsibilities; and planning strategies to (d) lead a “normal” life; (e) maintain a “decent” physical appearance; (f) ensure steady access to sterile injection equipment; and (g) injecting in safe locations and avoiding unsafe ones.

Motivation/Self-Efficacy to avoid sharing drug injection paraphernalia was measured with an adapted five-item Self-Efficacy scale (Vazan et al., 2012; Cronbach's alpha = .90) that assessed the extent to which participants felt they could successfully avoid sharing (a) needles, (b) cookers, (c) cottons, and (d) rinse water when injecting with people they knew and (e) could avoid using an injection partner's syringe, even if they had previously shared injection equipment with that person. Responses were scored on a 5-point Likert-type scale anchored by 0 = *not at all true* and 4 = *extremely true*.

Mediating Factors: Upstream Determinants of Risk—Efforts to Minimize PWID-Associated Stigma was assessed with a 10-item scale (Keeping It Together scale; Cronbach's alpha = .82) covering three domains: *living a normal life* [efforts to (a) live a normal life; (b) manage drug use; (c) think of things other than drugs; (d) maintain personal hygiene; (e) pay back borrowed money]; *taking care of veins* [(f) avoiding track marks caused by injection; (g) hiding track marks; (h) preventing abscesses; (i) avoiding crack/cocaine injection], and *distancing oneself socially from other injectors* [(j) hanging around known injectors in one's own neighborhood].

Social Support was assessed using an Access to Resources scale (Cronbach's alpha = .80). This 9-item scale assesses social support received from relatives, nonusing friends, and neighbors in three support subcategories: *material support* [(a) provided a place sleep; (b) gave money; (c) loaned money; (d) gave recommendations for work]; *emotional support* [provided emotional support (e) when unhappy and (f) when in trouble with the law]; and

drug use–related support [(g) recommended drug treatment; (h) helped to cope with withdrawal; (i) supplied with sterile syringes].

Mediating Factors: Risk Contexts—A third set of targeted outcomes captured participants' exposure to situations that are likely to increase their risk of blood-borne infection. Experiencing drug withdrawal is a particularly high-risk context, because users who normally maintain safe injection practices may override their own internalized norms in order to overcome the acute physical and psychological discomfort associated with opioid withdrawal. Other known risk contexts for PWID include injecting with a high number of injection partners, having access only to syringes used by others, and being in a drug-use situation in which the only syringes available are those that have been previously used by others.

Efforts to prevent drug withdrawal states were assessed using a 5-item Withdrawal Prevention Tactics scale designed for this study (Cronbach's $\alpha = .61$). Specific items ask respondents, with reference to the previous 3 months, how frequently they (a) save a bag for the next morning; (b) put aside additional drugs; (c) store methadone; (d) put aside money for drugs in an emergency; and (e) use painkillers or other drugs to ease withdrawal symptoms. We elected to use this Withdrawal Prevention Tactics scale despite the modest internal consistency because our prior research has indicated that PWID are more likely to engage in injection-related risk behaviors when experiencing withdrawal (Mateu-Gelabert et al., 2010), and, to our knowledge, no alternative measures to assess this construct exist.

Exposure to drug withdrawal states was assessed by asking participants how many times they had experienced withdrawal in the past 3 months. Responses were coded as follows: 0 times = 0; 1–5 times = 1; 6–10 times = 2; 11–20 times = 3; 21 or more times = 4. For analysis, responses were recoded as a dichotomous variable: “exposure to 0–5 withdrawals” and “exposure to 6 or more withdrawals.” Our prior qualitative research (Mateu-Gelabert et al., 2010) indicates that most opioid-dependent injectors in our target population experience numerous withdrawal episodes. Our selected cutoff point of 0–5 withdrawals within the past 3 months represents a reachable and desirable goal that we hypothesized would minimize the injection risk associated with numerous withdrawal episodes.

Three stand-alone items were used to assess exposure to risky injection networks: (a) *network size* was assessed as the total number of people participants reported injecting in the presence of within the past 3 months (range 1–150); (b) *risk with network* was evaluated by asking participants how often they found themselves in a drug-taking situation in which only syringes that had been used by others were available; and (c) *safety with network* was assessed as the percentage of network members to whom participants provided sterile syringes. The safety with network indicator was calculated by dividing a participant's response to the question “How many injectors did you provide with sterile syringes?” by his or her injection network size.

Primary Outcomes: Drug Intake and Perceived Control Over Drug Use—

Participants' frequency and amount of drug intake were assessed with two items: (a) the average dollar amount the participant reported spending on drugs on a given day (ranging

from \$0 to \$500); and (b) the participant's average number of weekly injections (calculated by multiplying the number of days the participant reported injecting in a typical week by the number of times he or she reported injecting in a typical day).

Participants' perceived ability to control drug intake was assessed with a single item. In order to facilitate statistical analysis for this stand-alone item in light of our modest sample size, the four response categories for this item—"No Control," "Very Little Control," "Moderate Control," and "A Lot of Control"—were recoded into two categories—"No Control" or "Very Little Control" versus "Moderate Control" or "A Lot of Control."

Primary Outcomes: Injection Risk Behavior—We inquired about six risky practices associated with parenteral infection (Pouget, Hagan, & Des Jarlais, 2012). The first item asked whether or not the participant had used, even once, a syringe that had previously been used by someone else. The remaining five risky practices were assessed by inquiring how many times participants (a) divided a drug solution using a syringe ("backloading"), (b) shared cookers, (c) shared cottons, (d) shared water, and (e) shared water containers. Responses for each of these five items were coded as follows: 0 times = 0; 1 time = 1; 2–5 times = 2; 6–10 times = 3; 11+ times = 4. For this analysis, responses to each of the five non-syringe-paraphernalia-related items were recoded as a dichotomous variable: "no risky injection practices in the past 3 months" (i.e., score of 0 for each item a, b, c, and d) and "risky injection in the past 3 months" (i.e., score of 1). Given the significant HCV risk associated with sharing injection paraphernalia, this recoding underscored an important distinction between those participants who eliminated paraphernalia-sharing practices versus those who continued to engage in sharing injection paraphernalia, if only a few times.

DATA ANALYSIS

We used single degree of freedom marginal homogeneity tests for ordered data with null distributions approximated by Monte Carlo resampling (Agresti, 2002), as implemented in the coin package in R (Hothorn, Hornik, van de Wiel, & Zeileis, 2006, 2008), to compare responses for 12 ordinal items before and after the intervention. Paired samples *t* tests were used to compare self-reported participation in risk-related behaviors during the period 3 months prior to intervention and the period 3 months after intervention. McNemar's test was used to compare responses for seven dichotomous items before and after the intervention. Stochastic dominance effect sizes (Vargha & Delaney, 2000) were calculated to convey the magnitude of changes on a common scale. For these effect sizes, a value of .50 indicates no difference and a value of 1.0 would indicate that whenever responses were different before and after the intervention, the response after the intervention was always more favorable to risk reduction. Thus, the effect size can be interpreted as the probability that the postintervention response was more favorable than the preintervention response when they were different. Stochastic dominance effect sizes of 0.56, 0.64, and 0.71 are considered small, medium, and large, respectively.

Analyses were also conducted to compare intervention completers ($n = 51$) versus dropouts ($n = 17$) (i.e., those for whom we have no posttest data, none of whom attended any intervention sessions) for all basic sociodemographic and primary outcome variables in

order to ascertain any potential biases in retention rates. Two-tailed, independent samples *t* tests or chi-square tests were conducted, as appropriate.

RESULTS

PARTICIPANTS

As assessed at pretest, participants ($N = 68$) were 78% White, 11% Latino, 4% African American, and 8% mixed race/ethnicity; 34% were female, and 75% were currently homeless. The mean age was 32 years ($SD = 9.5$ years; range = 19–58 years) with 38 participants (56%) between the ages of 18 and 30 and 30 participants (44%) age 31 years or older. Mean number of years since first injection was 12 ($SD = 9.4$ years; range = 1–48 years); 19% had injected between 1 and 4 years; 29% for 5–10 years; and 51% for 11 or more years.

Participation rates from this pilot study strongly suggest the feasibility of our intervention approach. No participants attended only one intervention session. Of all recruited subjects ($N = 68$), most (79%; 54/68) attended at least three of the group sessions and, of those who attended any intervention sessions ($n = 59$), approximately half (53%; 31/59) attended all five sessions. On average, participants attended 84% of the five scheduled intervention sessions. Because the total sample size is modest and there were so few participants who attended fewer than three of the planned sessions (7%; 5/68), comparisons of intervention effects by dose were not conducted.

EFFICACY OF THE STAYING SAFE INTERVENTION

As shown in Table 2, the Staying Safe Intervention showed promising evidence of efficacy. Sample size for all analyses is based on the 51 participants who completed posttest assessments.

Using a criterion of $p < .10$, we found that all differences in basic sociodemographic and primary outcome variables between intervention completers ($n = 51$) and those who did not attend any intervention sessions ($n = 17$) were nonsignificant.

Mediating Factors: Individual Determinants of Risk—Participants reported substantial increases in planning skills, indicating improvement in their perceptions of their abilities to plan ahead to avoid foreseeable injection-related risk (effect size = .73; $p < .001$).

Participants also reported increases in perceived motivation/self-efficacy to avoid sharing injection paraphernalia (effect size = .67; $p = .005$), supporting the notion that participants felt more empowered to make decisions that would reduce their risk of HIV and/or HCV exposure postintervention.

Mediating Factors: Upstream Determinants of Risk—Participants also showed a significant increase on the Keeping It Together scale, a measure of stigma management strategies, such as maintaining a “decent” physical appearance, hiding track marks, and distancing oneself socially from other users—strategies that may help individuals not to be

labeled as “drug users” by the dominant society, thereby helping to mitigate their social marginalization (effect size = .69; $p = .002$).

Participants did not report increases in access to material and/or emotional support provided by relatives, nonusing friends, or neighbors (effect size: .44; $p = .556$).

Mediating Factors: Risk Contexts—Postintervention results revealed a 27% reduction in the number of participants who suffered six or more withdrawal episodes within the prior 3 months (effect size = .75; $p < .001$), suggesting that the Staying Safe Intervention was successful in reducing participants’ exposure to withdrawal.

Despite the decrease in experiences of withdrawal, participants reported engaging in fewer withdrawal prevention activities (e.g., storing money, drugs, or methadone for times of need) at postintervention (effect size = .34; $p = .042$).

Staying Safe participants demonstrated marked improvements in network risk avoidance after the intervention. For example, participants reported a reduction, from 14 ($SD = 22$) to 4 ($SD = 5$) in the mean number of people with whom they injected (effect size = .83; $p = .003$). Results also showed an increase from 37% to 53% in the number of participants who provided sterile syringes to *all* those injectors with whom they injected (effect size = .67; $p = .047$) and an increase, from 22% to 47%, in the number of participants who, during the prior 3 months, were never in a drug-use situation in which only previously used syringes were available (effect size = .69; $p = .013$).

Primary Outcomes: Drug Intake and Perceived Control Over Drug Use—At the 3-month follow-up, participants reported significant reductions in both their average number of weekly injections (effect size = .80; $p < .001$) and their average daily drug expenditures. Before the intervention, participants spent a mean of \$77 ($SD: \75) on drugs per day; after the intervention, the mean daily expenditure was reduced to \$47 ($SD: \40; effect size = .70; $p = .022$). Participants also reported significantly increased perceived control over their drug intake (effect size; .65; $p < .001$) after the intervention.

Primary Outcomes: Injection Risk Behaviors—The Staying Safe evaluation inquired about six targeted risky injection practices: injecting with previously used syringes; “backloading” (i.e., using a syringe to divide drugs with another injector); sharing cookers; sharing cotton filters; reusing drug-dilution water; and sharing water containers. Posttest data revealed marked reductions in all of these behaviors. Participants reported a 30% drop in syringe sharing, (effect size = .65; $p < .001$) and a 32% drop in “backloading” (effect size = .66; $p < .001$). There were also significant drops in the sharing of nonsyringe injection paraphernalia, including a 47% decrease in the sharing of drug cookers to prepare the drug for injection (effect size = .74; $p < .001$), a 43% drop in the sharing of cotton filters (effect size = .72; $p < .001$), a 39% drop in sharing water used to dilute drugs (effect size = .70; $p < .001$), and a 31% drop in the sharing of water containers (effect size = .66; $p < .001$).

DISCUSSION

The primary goals of the Staying Safe Intervention are to reduce participants' injection risk behaviors, particularly the sharing of injection paraphernalia, and to train them in strategies to more effectively control their drug intake. The intervention also aims to empower PWID to address hypothesized mediating factors—namely, upstream and individual determinants of risk as well as risk contexts—that may affect their ability to engage in safer injection practices in a sustainable manner.

Participants' high rates of retention in the Staying Safe Intervention, along with their active engagement in the program's group discussions, support the feasibility of our intervention approach with active drug injectors, including those who are homeless (most study participants).

Our findings also suggest that the Staying Safe Intervention may have contributed to significant reductions in participants' injection risk behaviors, average number of weekly injections, and money spent on drugs. Additionally, the holistic approach of the Staying Safe Intervention appears to have helped PWID gain awareness of several potentially destabilizing mediating factors while training them in strategies to manage them. Participants demonstrated improvements in planning skills and motivation/self-efficacy to avoid injection-related risk; stigma management strategies to reduce the impact of drug use on their lives; and exposure to potentially hazardous injection situations, including drug withdrawal and risky injection networks.

The observed gains, however, were not entirely uniform; on two measures, participants' self-reported behavior changed in an unanticipated direction. First, participants did not report increases in social support, including access to material and/or emotional support provided by relatives, nonusing friends, or neighbors. This may indicate that social support is especially resistant to change, because it is not a self-determined behavior but is fundamentally dependent on the motivations and behavior of others. Another possibility is that participants' efforts to reduce PWID-associated stigma were not sufficient to change the perceptions of those within their social network within the course of the 3-month assessment period.

Second, despite the observed decreases in experiences of drug withdrawal, participants reported engaging in significantly *fewer* withdrawal prevention activities, such as storing money, drugs, or methadone for times of need, at the postintervention time point. This finding may indicate that participants' decreased drug intake and drug expenditures, possibly reflecting better management of their drug use, reduced their exposure to drug withdrawal episodes, which in turn reduced their need to engage in shorter-term coping tactics.

While the Staying Safe Intervention draws on existing public health intervention models and experience, the unique contribution of this program is to leverage lessons and strategies learned from “successful” (that is, HIV- and HCV-uninfected) long-term injectors themselves to address the immediate concerns of active injectors in terms of their own needs, priorities, and language. This evaluation of the first generation of Staying Safe

graduates suggests that the intervention may contribute to real differences in the behaviors and skills of active drug injectors. Furthermore, postintervention data indicating that participants reduced their number of injection partners and increased the number of fellow injectors to whom they provided sterile syringes also suggests that program participants carried their new skills and awareness back to their injection networks, helping to teach survival skills and promote safer behavior within their communities. Such network-based diffusion of intervention messaging may be essential to the long-term control of HCV and HIV among high-risk populations.

LIMITATIONS

The results of this preliminary study should be interpreted with caution in light of several limitations, chief among them the small sample size and pre-/posttest research design. While the lack of a control group limits our ability to eliminate alternative explanations for the observed outcomes, the strength and consistency of the risk reductions observed in multiple domains highlights the promise of our intervention approach. Moreover, the nonexperimental research design and modest sample size are appropriate for this early stage, exploratory study that was intended to evaluate the feasibility and preliminary efficacy of an innovative new intervention. Another limitation is the short follow-up period, which limits our ability to assess the durability of participants' improvements in safer injection practices. An additional limitation concerns the measurement of hypothesized mediators of intervention efficacy, such as efforts to prevent drug withdrawal and avoid PWID-associated stigma. Because many of these measures were developed or adapted specifically for this study, they were validated with only a single, relatively small sample of injectors recruited from one geographic area; therefore, the validity and reliability of these measures in larger and more diverse groups of injectors are unknown. However, it should be noted that all scales used to assess theorized mediating factors have strong face validity in that they measure behaviors and constructs known from prior research to affect injection-related risk behavior.

Despite these limitations, this evaluation suggests that the Staying Safe Intervention holds significant promise for supporting drug injectors in developing effective risk avoidance strategies. We believe the intervention was able to realize these gains because of three critical innovations. First, the Staying Safe Intervention does not focus exclusively on the moment of injection, but on the upstream determinants of risk behavior, such as stigma, risk networks, social support, and income, while encouraging injectors to plan ahead in order to better manage the drug-related risk contexts they are likely to face. Another innovative aspect of the program is the fact that abstract risk reduction messaging is placed within the larger interactional context of group injection, a setting in which most injection-related risk occurs. Third, the intervention highlights aspects of injection practice that are often underaddressed in harm reduction training, particularly the sharing of water and water containers, behaviors that have been demonstrated to carry significant risk for the transmission of HCV in particular (Doerrbecker et al., 2011, 2013).

Harm reduction programs in NYC and other urban centers of the United States have been important contributors to significant reductions in HIV prevalence and incidence among

drug injectors; however, these programs have to date been less successful in facilitating significant reductions in HCV infections among their clients. Given the substantial reductions observed among Staying Safe participants in key injection-related risk behaviors associated with HCV transmission, the Staying Safe Intervention may have the potential to contribute to sufficient additional risk reduction to help address the seemingly intractable rates of HCV transmission among PWID. The Staying Safe Intervention may thus provide an additional intervention model to be implemented in tandem with other efforts, such as SEPs and OST, to expand and bolster efforts to address the persistent HCV epidemic among PWID.

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FIGURE 1.
Staying Safe Intervention Model and Targeted Outcomes.

TABLE 1

Specific Content of the Staying Safe Intervention Sessions (Total of 5 Sessions With Activities)

Group Session 1: Applying Knowledge About HIV and HCV Transmission to Injection Equipment Use	
SAT Theoretical Targets: Knowledge, Motivation/Self-Efficacy	
Orient to study goals and “Staying Safe” approach	Identify at least five injecting situations leading to risk of HIV/HCV for injection drug users (IDUs)
Review basics of HIV/HCV transmission and prevention in the context of IDU	Identify role of syringe exchange programs (SEP) and opioid-replacement therapy (ORT) in risk reduction, and identify barriers to SEP and ORT for IDUs
Identify practices that put IDUs at risk for HIV and/or HCV infection	Set preliminary personal risk reduction goals (which will be revised through the intervention)
Group Session 2: The Injection Ritual and Avoiding Cross-Contamination of Equipment	
SAT Theoretical Targets: Knowledge, Motivation/Self-Efficacy	
Identify specific ways that cross-contamination of injection equipment can occur	Identify specific injecting risk situations that lead to risk behavior
Identify cross-contamination risks specific to IDUs	Identify specific strengths that IDUs can use to lower the risk of viral transmission for themselves, their immediate colleagues, and the larger community
Define meaning and value of an “injection safety zone”	Revisit preliminary personal risk reduction goals (revised through the intervention)
Group Session 3: Upstream Threats to Safe Injection and Strategies to Overcome Them (Part 1)	
SAT Theoretical Targets: Knowledge, Motivation/Self-Efficacy, Skills, Social Interaction Processes relevant to upstream targets	
Identify upstream contexts, situations, and circumstances that cause serious threats to safe injection	Identify specific skills and strategies to overcome the injection risks posed by the following situations: dope sick; needle shortages; homelessness/unstable housing; losing social ties with nonusers; facing stigma by not taking care of yourself; losing a job or other steady income; and arrest, incarceration, and release
Understand how these upstream contexts, situations, and circumstances can lead to unsafe injection practices	Revisit preliminary personal risk reduction goals (revised through the intervention)
Group Session 4: Upstream Threats to Safe Injection and Strategies to Overcome Them (Part 2)	
SAT Theoretical Targets: Knowledge, Motivation/Self-Efficacy, Skills, Social Interaction Processes relevant to upstream targets	
Use facilitators and peers to model skills and strategies identified in Session 3 to overcome injection risks	Plan how to apply these skills and strategies in the context of personal goals
Practice these skills and strategies	
Group Session 5: Thinking Strategically and Planning Ahead	
SAT Theoretical Targets: Knowledge, Motivation/Self-Efficacy, Skills, Social Interaction Processes	
Learn how to strategically plan ahead to avoid potential threats in the near future	Plan how to integrate HIV and HCV maximum risk reduction practices into injection networks
Identify concrete action steps to maintain safe injection and safe sex over the long term, even if confronting desperate situations	Identify five specific ways to make injection networks safer from HIV and HCV transmission
Describe specific solutions to challenges that could impede action steps	Revisit and refine personal risk reduction goals in the context of “lessons learned” during the intervention

TABLE 2

Staying Safe Intervention: Pre- and Postintervention (3 Months) Paired Samples Statistics ($n = 51$)

Mediating Factors	Test statistic value	<i>p</i> value	Stochastic dominance effect size ^a
Individual Determinants of Risk			
<i>Planning Skills</i>			
Planning Scale ^b	5.14	< .001	.73
<i>Motivation/Self-Efficacy</i>			
Self-Efficacy Scale ^b	2.92	.005	.67
Upstream Determinants of Risk			
<i>Stigma</i>			
Keeping It Together scale ^b	3.34	.002	.69
<i>Social Isolation</i>			
Access to Resources ^b	0.59	.556	.44
<i>Maintaining Income</i>			
On average, how much did you spend on drugs on a given day ^b	2.36	.022	.70
Ability to manage drug intake as “moderate” or “a lot” of control ^c	10.71	< .001	.65
Average weekly injections ^b	4.53	< .001	.80
Risk Contexts			
<i>Withdrawal</i>			
Withdrawal Prevention Scale ^b	2.08	.042	.34
Suffered opioid withdrawals ^d	15.94	< .001	.75
<i>Injecting Networks</i>			
Number of people with whom you have injected drugs ^b	3.02	.004	.83
Had drugs yet only syringes used by others were available ^d	6.04	.014	.69
Percent of those with whom injected drugs provided sterile needles ^b	2.02	.047	.67
Primary Outcomes			
Risky Injection Practices			
Shared needles even once ^c	10.89	< .001	.65
Divided up drugs using a syringe (known as “backloading”) ^c	11.64	< .001	.66
Shared cookers ^c	22.00	< .001	.74
Shared cottons ^c	18.18	< .001	.72
Shared water ^c	12.80	< .001	.70
Shared water containers ^c	19.20	< .001	.66
Injection Risk and Drug Intake Behaviors			
On average, how much did you spend on drugs on a given day ^b	2.36	.022	.70

Mediating Factors	Test statistic value	<i>p</i> value	Stochastic dominance effect size ^a
Average weekly injections ^b	4.53	< .001	.80
Perceived ability to manage drug intake as “moderate” or “a lot” of control ^c	10.71	.001	.65

Note.

^a Stochastic dominance effect sizes of 0.56, 0.64, and 0.71 are considered small, medium, and large, respectively.

^b Paired samples *t* test.

^c McNemar test for binomial distribution.

^d Single degree of freedom marginal homogeneity tests for ordered data with null distributions approximated by Monte Carlo resampling (Hothorn, Hornik, van de Wiel, & Zeileis, 2006).