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Couple-based HIV counseling and testing: a risk reduction intervention for U.S. drug-involved women and their primary male partners

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Abstract

To help reduce the elevated risk of acquiring HIV for African American and Latina women drug users in primary heterosexual relationships, we developed a brief couple-based HIV counseling and testing prevention intervention. The intervention was based on an integrated HIV risk behavior theory that incorporated elements of social exchange theory, the theory of gender and power, the stages-of-change model, and the information-motivation-behavior skills model. In this article we describe the development, content and format of the couple-based HIV testing and counseling intervention, and its delivery to 110 couples (220 individuals) in a randomized effectiveness trial, the Harlem River Couples Project, conducted in New York City from 2005 to 2007. Components of the couple-based intervention included a personalized dyadic action plan based on the couple's risk profile, and interactive exercises designed to help build interpersonal communication skills, and facilitated discussion of social norms regarding gender roles. The couple-based HIV testing and counseling intervention significantly reduced women's overall HIV risk compared to a standard-of-care individual HIV testing and counseling intervention.

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Experiences and perceptions of the intervention were positive among both clients and interventionists. The study was the first to demonstrate the effectiveness and feasibility of delivering a brief couple-based HIV counseling and testing intervention to reduce risk among drug-using heterosexual couples in high HIV prevalent urban communities in the United States. The intervention can be expanded to include new HIV prevention strategies, such as pre-exposure prophylaxis. Further research is needed to evaluate cost-effectiveness and implementation of the intervention in clinical settings.

Keywords

HIV prevention; voluntary HIV testing and counseling; women's health; substance use

Introduction

In the United States (U.S.), women account for 21% of those living with HIV/AIDS, nearly triple the level of the mid-1980s (Centers for Disease Control and Prevention [CDC], 2013). African American and Latina women, in particular, have been disproportionately affected by the epidemic: they comprise 27% of the female population but account for 81% of women living with HIV/AIDS (CDC, 2009). Gender-based social inequalities and other structural, epidemiological and psychosocial factors place African American and Latina women at increased risk of acquiring HIV (Higgins, Hoffman, & Dworkin, 2010). These data highlight an urgent need to develop HIV prevention methods that empower racial/ethnic minority women.

Nearly 90% of all incident HIV infections among U.S. minority women are heterosexually acquired, most often in the context of an intimate relationship (CDC, 2013; El-Bassel et al., 2001; Finer, Darroch, & Singh, 1999; Kalichman, Rompa, Luke, & Austin, 2002; McMahon & Tortu, 2003; McMahon, Tortu, Pouget, Hamid, & Torres, 2004; Misovich, Fisher, & Fisher, 1997; Wilson, Lavori, Brown, & Kao, 2003). Evidence has shown that women in primary relationships engage in higher sexual risk behavior, such as reduced condom use and higher frequency of unprotected anal intercourse, compared to those in casual or other non-primary relationships (Houston, Fang, Husman, & Peralta, 2007; Koblin et al., 2010), leading to higher HIV incidence within primary relationships than in other types of relationships (Kalichman et al., 2002; Wilson et al., 2003). For example, in our study of substance-using African American and Latina women in New York City, HIV incidence was 2.54 infections per 100 person years in women with a steady male partner compared to 1.06 infections among women with casual or commercial sex partners, a relative risk of 2.40 (McMahon & Tortu, 2003). Illicit drug use represents another important risk factor for HIV infection among African American and Latina women (Anderson et al., 1999; Holmberg, 1996; Strathdee & Sherman, 2003). Local HIV/AIDS epidemics in urban areas tend to be concentrated among drug-users and their sexual partners (Miller & Neaigus, 2001; Van Tieu & Koblin, 2009). Research examining social networks reveals the highest sexual risk among individuals who provide, receive or use drugs (Pilowsky et al., 2007). Drug-involved African American and Latina women in primary, heterosexual relationships thus constitute

one of the most vulnerable risk groups for HIV and merit high priority for HIV prevention intervention research.

Responding to the high rates of HIV transmission in heterosexual, intimate partnerships, HIV prevention efforts have shifted away from an emphasis on individual-centered intervention approaches to more relevant, dual-gender, couple-, and family-based interventions (National Institute on Drug Abuse, 2002). In light of men's salient influence on sexual decision-making, particularly in intimate relationships, these prevention programs include contextual and relationship factors as well as male gender perspectives that influence couples' sexual decision-making.

Another important development in HIV prevention research is the finding that brief interventions can be effective at reducing HIV risk (Kamb et al., 1998; Meader, Li, Des Jarlais, & Pilling, 2010). In a meta-analytic review of HIV prevention interventions designed for drug users, Meader et al. (2010) found that both multi-session and brief interventions were equally effective in reducing injection and sexual risk behavior, and concluded that "... brief educational interventions are more likely to be cost-effective and may be more readily implemented in a variety of different contexts", suggesting "limited support for the widespread use of formal multi-session psychosocial interventions..." (p. 2). Brief interventions accommodate the life experiences of vulnerable, socioeconomically disadvantaged, drug-involved people at high risk for HIV, who often find it challenging to attend multi-session prevention programs (Jemmott, Jemmott, Hutchinson, Cederbaum, & O'Leary, 2008). Although advances have been made in the development of brief couple-based interventions in Africa, there is a lack of evidence-based brief HIV prevention interventions designed to address the unique needs of drug-involved U.S. women in steady heterosexual relationships (LaCroix, Pellowski, Lennon, & Johnson, 2013; Meader et al., 2010).

To address these pressing HIV prevention needs, we designed and evaluated a brief couple-based HIV risk reduction intervention modeled on the HIV counseling and testing (HIV-CT) delivery modality. The effectiveness of this intervention for reducing HIV risk among drug-involved couples was demonstrated in a randomized clinical trial (NCT00325585) conducted by our team; the results of which have been published elsewhere (McMahon et al., 2013). In the present article, we describe the couple-based HIV-CT intervention in detail, including the theoretical framework guiding its development, intervention content, format and delivery, implementation, and lessons learned from the conduct of the randomized trial.

Theoretical Framework

Development of the couple-based HIV-CT intervention was guided by an integrated theory of HIV risk behavior that incorporated elements of social exchange theory (Emerson, 1976), the theory of gender and power (Connell, 1987; Wingood & DiClemente, 2000), the stages-of-change model (Prochaska, Redding, Harlow, Rossi, & Velicer, 1994), and the information-motivation-behavior skills model (Fisher & Fisher, 1992). Social exchange theory holds that behavioral decisions depend on the perceived trade-offs of costs and

rewards of the behavior compared to alternatives within the context of social interactions and mutual obligations. For dyadic behavior involving couples, this must encompass the pros and cons for each individual as well as for the relationship, which adds a level of complexity to decision-making.

The theory of gender and power depicts differential gender roles and norms that create a disadvantage for women in terms of social power and access to resources within intimate relationships and in society. The complexity of decisions concerning heterosexual couple's behaviors (e.g., whether or not to use condoms) is compounded by the gendered dynamics of the relationship (e.g., power inequity, gender norms) and by each member of the dyad having a different set of costs and rewards driving their decision frame. These sets of costs and rewards may be weighted differently based on individual perspectives. This decision-making process may lead to dyadic conflict, with resolution attained through negotiation, application of peer or gender norms, relationship power inequities, or relationship dissolution. Often, these processes may lead to an equilibrium in which couples settle into habitual behaviors with scripted social exchanges often based on gender expectations (Canary & Emmers-Sommer, 1997).

The theories of social exchange and gender and power set up the behavioral options within an established gendered context. However, since risk behaviors are often established and scripted within a relationship (Emmers-Sommer & Allen, 2005), it is often difficult for couples to enact change from within the relationship. Therefore, implementation of sexual risk reduction requires modification of interpersonal sexual scripts (Bowleg, Lucas, & Tschann, 2004), and commitment from both members of the couple. The dyadic dynamics underlying this equilibrium fall along a continuum of psychosocial readiness for dyadic behavior change. Using Prochaska's (1994) behavioral change model, the counselor promotes the identification of staging change readiness and facilitates movement along this continuum. In recognition of the dyadic nature of this behavioral change, this staging has to be done at the lowest common denominator within couples.

The final theory integrated into the couple-based CT-HIV intervention is Fisher and Fisher's (1992) model, which underscores the importance of information, motivations, and skill acquisition for instituting behavioral change at the couple's point of readiness. Once the couple's point of readiness for change has been established, the intervention targets these three areas necessary for behavioral change. The counselor provides current information on HIV, other sexually transmitted infections (STIs), and sexual risk reduction, and conducts motivational interviewing to facilitate progression along Prochaska's continuum. Finally, skills are taught targeting couple's selected risk reduction behavior, including condom negotiation and communication.

The couple-based HIV-CT intervention fully integrates these four critical theories of behavior change to promote a new, healthier equilibrium by reframing cost-reward perceptions, subjective norms, and social exchanges. For instance, the counselor guides the couple in reframing the relationship commitment in terms of mutual health and protection. This may potentially lead to renewed dyadic conflict, at least in the short-term, and it is essential for interventions to manage this conflict by providing couples with interpersonal

strategies and skills to attain resolution through negotiation and effective communication. Relevant information and motivation may facilitate realignment of dyadic social exchanges, as well as subjective norms, leading to progression of readiness to enact health behavior change. Acquiring requisite cognitive mapping and behavioral skills is assumed to be a precondition for enactment.

Methods

Target Population and Study Design

The couple-based HIV-CT intervention was designed to reduce HIV/STI risk behavior in women substance users in sexually active steady relationships with male partners. Specifically, the intervention was developed for adult women 18 years of age or older who use crack, cocaine or heroin, and are at risk of sexual or injection-acquired HIV/STIs from a current male partner identified as a primary partner (“a husband, common-law husband, or steady boyfriend” of at least six months). We excluded women if they perceived any threat that might occur due to participating in joint couple HIV counseling (McMahon, Tortu, Torres, Pouget, & Hamid, 2003). Since the program was designed as a primary prevention intervention, all women self-reported as HIV-negative, but their primary male partner could be HIV-positive, negative or sero-unaware. The intervention was developed to be administered in either English or Spanish, so fluency in one of these languages was a requirement.

As part of a randomized controlled trial, the couple-based HIV-CT intervention was administered to 110 eligible couples (220 individuals) to test the efficacy of the intervention against a National Institute on Drug Abuse (NIDA) standard-of-care control intervention, which was administered to 116 women. The trial was conducted in Harlem and South Bronx in New York City from March 2005 to September 2007. Procedures for the recruitment and enrollment of couples into the trial have been described in detail by McMahon et al. (McMahon et al., 2013; McMahon et al., 2003). Women who were eligible and willing to participate were asked to enlist their male partner into the study, following a set protocol. Couples were scheduled to visit a project field office for enrollment, assessment, randomization, and intervention administration. Follow-up assessments were conducted at three- and nine-months post-intervention. Participants were paid \$35 for each assessment interview they attended. A Certificate of Confidentiality was obtained from the U.S. Department of Health and Human Services (DA-04-218), and all study protocols were approved by an Institutional Review Board.

Couple-Based HIV Counseling and Testing Intervention

The couple-based HIV counseling and testing intervention was developed by the authors based on prior qualitative and quantitative work with couples, published and unpublished literature, and independent expert review by scientists, clinicians, and counselors. The intervention approach is consistent with the prevention counseling model established by the Centers for Disease Control and Prevention, which emphasizes personalized risk assessment and tailored content, interactive counseling, positive message framing, skills-building, and the negotiation of achievable behavioral change goals (Centers for Disease Control and

Prevention, 1993; Rietmeijer, 2007). The major components of the intervention are listed in Table 1. Consistent with the standard model of voluntary HIV counseling and testing, the couple-based HIV-CT was divided into pre- and post-test sessions. The intervention was administered in a setting similar to that of a health clinic, including a reception and waiting area separate from multiple offices and medical room.

The pre-test joint couples counseling session began with a brief introduction and overview to the intervention. The counselor then administered a short dyadic risk assessment that permitted the intervention to be tailored to each couple's risk profile, stage of behavior change for various risk behaviors, and self-reported dyadic HIV serostatus (i.e., concordant negative/male positive discordant). Basic information about HIV and other STIs, including hepatitis B and C, was provided to all couples. Thereafter, each couple was administered a series of risk reduction components personalized to their dyadic risk profile.

After completion of the tailored components, dyadic interactive exercises were conducted that addressed negative norms related to risk behaviors as well as couples' communication skills that may inhibit enactment of preventive behavior. Throughout the sessions, the counselor maintained an action plan of activities each couple had agreed to perform after completion of the intervention—for example, to desist or limit unprotected anal intercourse or engage in safe drug injection practices. Some action plan elements involved active referrals by the counselor, such as enrolling in a drug treatment program. The last component of the couple's joint counseling session provided pre-test information regarding HIV and hepatitis B and C antibody testing.

The final component of the intervention was conducted with each member of the couple individually. During these individual sessions the counselor addressed sex and drug-related risk that the client might have engaged in outside of their primary relationship. Finally, the counselor or phlebotomist collected biological samples for HIV and hepatitis B (HBV) and C (HCV) testing. Consistent with the HIV-CT model, each member of the couple was asked to return to receive test results, and at this visit the counselor delivered post-test counseling in which individual test results were provided and the action plan was reviewed for compliance and modification.

Introduction/overview—The objectives of the introduction/overview were to (a) make the couple feel comfortable by establishing rapport and setting a non-judgmental, collaborative, but authoritative tone, (b) explain the purpose of the intervention, and (c) provide an overview of the general topics to be addressed. The counselor elicited cooperation and provided rationale by presenting a problem to the couple (e.g., the high rates of HIV/STI among couples in the community) and asked for their help in finding ways to protect themselves and others in the community. In this way, the couple served both as advisor and as agents of change.

Dyadic risk assessment—A fundamental approach to the intervention was to customize program content to the risk behavior profile, stage of readiness for behavior change, and dyadic HIV serostatus of the couple. This was achieved by having each member of the couple complete an individual 10-item survey, developed by the investigative team. The

survey contained questions on dyadic (within-couple) risk, such as HIV testing behavior, engagement in vaginal and anal intercourse, frequency of condom use, injection and non-injection drug use, and conception desires. The counselor informed couples in advance that individual responses to these items would not be shared with the other partner. The responses were privately handed to the counselor. An algorithm was created to translate responses to the 20 items (10 x 2 partners) into tailored program content. For example, if both members responded that they did not engage in anal sex with one another, then the anal intercourse risk reduction component was omitted from program content. However, if one or both partners responded positively to this item, then the component was incorporated into the program. In addition, the content of each delivered component was tailored to the couple's stage of readiness for behavior change. For example, if both members reported using condoms consistently during vaginal intercourse, then the program delivered content tailored to reinforce maintenance of this behavior. However, if one or both members of the couple reported intermittent or no condom use, then the content was tailored to promote safer sex behavior change.

Content was also customized to the dyadic HIV serostatus of the couple. Since the intervention was designed to reduce women's primary risk of HIV infection, all of the women who participated in the intervention were HIV-negative. To elicit the HIV status of the male partner, the counselor initiated a conversation about past HIV testing and whether each member of the couple had knowledge of the other's status. Eight of the 110 male partners (7.3%) who participated in the couple-based intervention self-reported as HIV-positive (subsequently confirmed through HIV testing), and all of the enrolled female primary partners of these men reported being aware of their partner's status. HIV-serodiscordant couples were administered tailored content for all relevant components, and were also delivered additional components addressing antiretroviral therapy adherence for the infected partner and safe conception options and referrals for couples wishing to conceive. Based on counselors' experience and fidelity monitoring, the dyadic risk assessment approach to tailoring intervention content was time-efficient, reliable and effective.

Video information component—Regardless of the couple's dyadic risk profile, all couples were shown a 10-minute video providing up-to-date information on HIV and other STIs (Chlamydia, gonorrhea, genital herpes, syphilis, trichomoniasis, yeast infection and hepatitis B virus), as well as hepatitis C virus. The objective was to provide couples with culturally relevant up-to-date basic knowledge of HIV/STI/HCV transmission and prevention. The video was a compilation of segments from several videos on STIs, including HIV and hepatitis, and incorporated a vignette featuring a scenario in which an African American couple and their friends discuss risks for HIV/STIs. Appropriate informational videos can be selected for relevance to the population, or replaced with other media materials.

Risk reduction components—Each risk reduction component was designed to address specific individual or dyadic HIV/STI risk or preventative behavior. Components included (1) regular recurrent HIV/STI testing, (2) condom use to prevent HIV/STIs, (3) anal sex and

HIV risk, (4) safe injection drug use practices, (5) safe non-injection drug use practices, (6) sexual risk reduction when trying to conceive, (7) adherence to antiretroviral treatment (for serodiscordant couples), (8) hepatitis B and C treatment, and (9) substance dependence and treatment. All couples received the first two components covering HIV/STI testing and condom use. Although condom use may be associated more with pregnancy prevention than HIV/STI risk reduction in many couples, the intervention was designed for couples who voluntarily (or through referral) seek HIV testing and counseling. Thus, any shift in focus toward condoms for HIV/STI risk reduction was consistent with participant expectations. Condom use components included condom skills building and a “menu” of sensual and sexual activities designed to eroticize safe sex, strategies that have been effective in reducing sexual risk behavior (Johnson et al., 2009; Scott-Sheldon & Johnson, 2006). The remaining components (5.3-5.10 in Table 1) were delivered only to couples who reported engaging in the target behavior. An additional optional component was developed for at-risk couples who were not HIV-serodiscordant and who were resolute in their opposition to condom use. Such couples received the Eight-Step TLC (Testing/Lack of outside risk/Condom-free) component, which described the steps involved to ensure that neither partner has an STI and to pledge not to engage in sexual risk outside the relationship. We included this component to minimize HIV/STI transmission risk for couples who were adamant in their refusal to use condoms. In such cases it is better to introduce an alternative approach that initiates a conversation about HIV/STI risk and protection in the relationship, than to insist on behavior change for which there is little to no chance of compliance.

Guided by our theoretical framework, most risk reduction components began by providing information designed to enable participants to recast their cost-reward assessment of the target behavior. First, the counselor provided community-level evidence (e.g., rates of HIV/STI infection among couples) related to the target behavior, and discussed the protective benefits, relative to the costs of alternative behaviors, using a positive messaging frame. The content of selected components was further customized to accommodate couples’ stage of behavior change. For example, the intervention content for at-risk couples who were not using condoms (pre-action stage) focused on behavior change (e.g., addressing cost-reward balance, and normative and relationship barriers to change) whereas the intervention content for couples using condoms intermittently or consistently (post-action stage) focused on increasing or maintaining existing condom use (e.g., positive reinforcement). Content for HIV-serodiscordant couples was also tailored to provide more precise information on risk of infection and the importance of adherence to ARV therapy for the positive partner.

Interactive exercises—Upon completion of the relevant risk reduction components, all couples were delivered two counselor-mediated interactive sessions: the first was designed to address subjective and community norms related to gender issues and sexual risk behavior, and the second to build interpersonal communication skills. The subjective norms session was presented in a game format called the “Community Challenge Game”. Couples were informed that 100 members in their community were surveyed on seven questions, and that the object of the game was to correctly guess which of several responses to each question was most commonly selected by members of their community. An example

question was: “Thinking about your current or last steady relationship, if your partner had sex with someone else, what would you prefer they did? (a) Be honest and tell me about it so we could work through it together, (b) Be honest and tell me about it so I could leave him/her, (c) Don’t tell me about it, as long as he/she used a condom or doesn’t put me at risk.” Using clipboards, each member of the couple privately and independently selected the response they thought was most commonly selected by community members. They were then asked to disclose their answers to one another, and the counselor revealed which response the community selected. The purpose of this exercise was to reveal within-dyad differences and similarities regarding perceived social norms related to gender roles and sexual behavior, as well as reinforce or challenge couples on their perceptions of community norms. Counselors guided the discussion toward a normative framework supporting healthy decisions.

The second interactive session involved practiced couple communication. Studies of communication have shown the importance of training or practice in negotiation of condom use and safer sex behaviors in heterosexual couples (Emmers-Sommer, Maier, & Allen, 2014; Allen, Emmers-Sommer, & Crowell, 2002). We adapted elements of the Speaker/Listener technique originally developed by Markman, Stanley, and Blumberg (1994; Stanley, Markman, & Blumberg, 1997) to improve couple’s interpersonal communication skills. This method distinguishes the roles of speaker and listener, with a set of rules governing the conduct of each during communication. Guided by findings from qualitative interviews with couples, we adapted these rules for use with our target population, and formulated a set of Ten Good Communication Practices. After introducing the exercise, the counselor briefly summarized each practice, while listing them on a white board. Two columns labeled with the first name of each member of the couple were added to the right of the list. The counselor then asked each member to rate their own communication skill for each of the ten practices. “I’d like you to think about your own habits for communicating and whether or not you already practice these skills, because for each skill I’m going to ask you to rate yourself on a scale from 1 to 10, where 1 is the lowest score, meaning you’re very bad at it or you never practice it at all, and 10 is the highest score, meaning you’re very good at it.” Scores were elicited from the couple and written on the white board. Each member of the couple was then asked to comment on their partner’s self-rated scores, and point out scores with which they disagreed. The counselor must ensure that the discussion does not become overly contentious. The objective was simply to make each partner aware of the other’s perception of their communication practices, whether to reinforce poor or favorable self-perceived skills or highlight disagreements. Participants were then shown a five-minute video clip of a couple using good communication practices during a discussion. The couple then engaged in a role playing exercise, moderated by the counselor, in which they applied the Speaker/Listener technique in a conversation. The content of the role-playing conversation was one of several scenarios selected by the counselor, or one that the couple had chosen. The session ended with constructive, non-judgmental, advice by the counselor to improve communication.

Action plan review—The penultimate component of the joint couples counseling session was to review the couple’s personalized Action Plan. Described to participants during the

introductory session, the Action Plan form is a document maintained by the counselor throughout the joint counseling session. The Action Plan is based on the couple's tailored HIV/STI risk reduction components, their dyadic HIV serostatus, their stage of readiness for behavior change, and discussions with the counselor. The plan identifies "actions" that the couple should consider enacting to enhance protective behavior. This might include, for example, trying a newer generation of safe but more sensitive latex condoms (free samples were supplied), reduce unprotected anal intercourse, avoid sharing syringes, follow the Eight-Step TLC plan, use a pill planner or alarm to increase ART adherence, or practice the Speaker/Listener technique at home. The counselor reviewed the couple's Action Plan with them and elicited agreement to perform the recommended actions. Two copies of the plan were included in a packet given to the couple.

HIV/HBV/HCV testing part I: pre-test counseling—The final component the couple's joint session consisted of HIV and hepatitis B and C pre-test counseling. The content and format of this component was adopted from the NIDA Community-Based Outreach Model basic information session, cards 15–18 (National Institute on Drug Abuse, 2000). Basic information was given to the couple about the nature of the tests for HIV, HBV, and HCV and the meaning of a positive or a negative result on each test.

HIV/HBV/HCV testing part II: specimen collection/secondary HIV risk—After joint pre-test HIV/HBV/HCV counseling, members of the couple were separated for collection of biological samples for testing. For HIV-serodiscordant couples, the negative partner was escorted to a medical/phlebotomy room for saliva (HIV) and blood (hepatitis) specimen collection for antibody screening. Rapid HIV testing was available during the trial period of the intervention, but conventional testing was still in wide use. We opted to use the OraSure HIV-1 Oral Specimen Collection method for HIV ELISA testing, confirmed by Western Blot, which required an oral swab and returned results in one to two weeks. A blood draw was required for anti-HBV and HCV screening, conducted by Abbott Laboratories using the HCV EIA 3.0/VITROS and HBV AXSYN assays. While the HIV-negative partner was being tested, the counselor used this time to initiate a brief discussion with the HIV-positive partner about potential risk behavior with secondary partners. The counselor assured the client that any disclosures would be kept in strict confidence. The counselor then initiated a discussion about potential injecting partners, and the importance of using safe injection practices (for injectors). The discussion then turned to potential risk of transmission with secondary sex partners, and the importance of consistent condom use and ART adherence. The counselor then left the HIV-positive partner and engaged the HIV-negative partner in the medical room, with a similar discussion. The objective of this counseling component was to address HIV risk and reinforce protective behavior with partners outside of the primary relationship, continuing the theme of promoting healthy behavior for one's self, partner, and family. For HIV-seronegative/unaware couples, a similar process was conducted, but with each member of the couple taking turns at specimen collection (medical room) and secondary HIV risk counseling (counseling room). It is essential that the two rooms are sufficiently private to ensure confidentiality (and perceived confidentiality).

Once specimen collection and secondary risk counseling were completed, appointments were scheduled for individual post-test results and counseling. Follow-up appointments for post-test visits were made on an individual basis about 10 to 14 days after the initial intervention. Each member of the couple was allowed to schedule an appointment individually, or together with their partner, but all post-test sessions were conducted individually. In addition, the couple was asked to select a date for another couple-based HIV counseling and testing session in 6–12 months. This was normalized by drawing a parallel with a bi-annual or annual physical exam.

HIV/HBV/HCV testing part III: post-test counseling—Post-test counseling was composed of two parts. The first consisted of standard post-test counseling adopted from the NIDA Community-Based Outreach Model basic information session, cards 19–24 (National Institute on Drug Abuse, 2000). During this session, clients were told their HIV, HBV and HCV test results and the meaning of a negative or a positive result. The specific content for a newly diagnosed viral infection covered HIV or hepatitis treatment referrals, social and mental health service referrals, and New York State's Partner Assistance Program (PNAP). The PNAP service assists persons newly diagnosed with HIV with in-person partner notification. If the newly diagnosed client was accompanied by their partner, the client was given the option of immediately informing their partner with the assistance of the counselor or, alternatively, using the PNAP service or informing their partner in their own way.

The second part of the post-test visit was to review the Action Plan from the prior joint couples counseling session. In light of a newly diagnosed infection, the plan may have to be revised, but only after partner notification. The counselor must also judge whether the client is emotionally ready to discuss a revised plan. The counselor may ask to follow-up with the client or the couple to discuss this, as well as following up on the referrals at a later date. For clients in which no newly diagnosed infections are revealed, the counselor reviewed and evaluated progress on the Action Plan from the prior couple-based session. A discussion was conducted around new or continuing barriers to healthy behaviors, and potential solutions and alternatives.

Interventionists and Intervention Fidelity

One male bilingual (English and Spanish) counselor performed 95% of the couple-based HIV counseling and testing interventions, as well as the NIDA control intervention. The remainder was performed by one female bilingual back-up counselor. The principal male counselor had over twenty years of experience in community outreach, case management, education, drug treatment, and HIV counseling. He was also a trained phlebotomist and performed biological specimen collection for HIV and hepatitis B and C anti-body screening. The back-up counselor had similar education and experience. The couple-based HIV-CT intervention was manualized to enhance training (McMahon, Tortu, Rodriguez, & Hamid, 2006). Both interventionists received extensive training on the couple-based HIV-CT intervention and standard-of-care control using an interactive skills-building approach. This included study/familiarization sessions of the manualized intervention and potential scenarios (e.g., conflict resolution) with senior staff, role-playing rehearsals with staff posing as participants, and pilot rehearsals with eight couples prior to client enrollment. In

addition, counselors received ongoing formal course training in HIV counseling and testing, overview of HIV/AIDS and sexually transmitted infections, HIV/AIDS evidence-based medicine and HIV prevention, HIV disclosure and confidentiality law, domestic violence, cultural competency, substance abuse, motivational interviewing techniques with drug users, and harm reduction strategies with drug users. Monthly project meetings were held in which counselors discussed, and received feedback on, emergent issues and challenges and their handling of various situations. Ten percent (10%) of the interventions in each treatment condition were randomly selected for monitoring by the Project Director or Principal Investigator to assess fidelity. Fidelity assessments included a checklist (based on the intervention manual) and monitor notes. Adherence to protocols and intervention fidelity were discussed with counselors at monthly project meetings.

Results

Baseline Description of Couples Assigned to the Couple-Based HIV Counseling and Testing Intervention

Among the 110 couples randomly assigned to the couple-based intervention, the mean age in years was 38.8 (Std Dev: 8.6) for women and 40.5 (Std Dev: 8.0) for men. About one-fourth (23%) of the couples were legally married, two-thirds (66%) were living “common law”, and 11% were not married/common law. The average length of the relationship was 7.0 years (Std Dev: 7.5). Mean annual household income was \$14,764 (Std Dev: \$6,976). The majority of couples (82%) self-identified as belonging to the same racial/ethnic group—Hispanic (44%), African American (35%), White (3%); whereas 18% were of mixed race/ethnicity. Eight couples (7.3%) were HIV-serodiscordant. Nearly one-in-five couples (19%) were trying to conceive. Twenty-five couples (23%) reported injecting drugs together in the past three months. Most couples (76%) reported no use of condoms in the last three months, and only six couples (5%) reported using condoms consistently for both vaginal and anal sex. Among couples who engaged in anal intercourse (36%), the majority (86%) did not use condoms consistently. More than one-third (36%) of women reported having vaginal or anal sex with a man other than their primary partner during the relationship, and about 70% of these secondary partners were men with whom women exchanged sex for drugs or money. In the three months prior to the intervention, 33% of women reported having sex with a secondary partner (range: 1 to 20), with 47% reporting consistent condom use, 31% reporting some condom use, and 22% no condom use. Nearly 31% of men reported having vaginal or anal sex with a woman other than their primary partner during the relationship; 11% reported this behavior within the prior three months (range: 1 to 5). For men, condom use with secondary partners was: 30% consistent use, 17% some use, and 52% no use.

Intervention Effectiveness

Results on the HIV risk reduction effectiveness of the couple-based HIV-CT intervention have been reported elsewhere (McMahon et al., 2013). To summarize, at terminal (nine-month) follow-up assessment, couples who participated in the couple-based HIV-CT intervention reported lower overall HIV risk behavior compared to those assigned to the standard-of-care NIDA HIV-CT intervention. We estimated that the couple-based intervention prevented 3.04 more HIV infections per 1000 person years than the standard

NIDA intervention. Analysis indicated that this prevention gain was primarily due to reductions in receptive syringe sharing, both within and outside the relationship, as well as reductions in unprotected anal sex with primary partners. There was also evidence of a decrease in unprotected vaginal sex with primary partners and in the number of secondary sex partners.

Couples' Perspectives

In general, couples expressed positive perspectives and experiences regarding couple-based HIV counseling and testing. Common perspectives included a desire to be safe and healthy, an appreciation for the skill and personal attributes of the counselors, the benefit of having a neutral third party initiate a discussion about HIV and hepatitis risk, that the intervention was informative but also fun, and receiving a take-home packet of materials (e.g., new types of ultra-sensitive condoms). Couple's particularly liked the communication skills-building interactive session. Several couples expressed appreciation of the Eight-Step TLC component, which was regarded as a more realistic option than condom use for some. This option was also seen as a sign of respect for the couples' autonomy in taking responsibility for their own health behaviors. A small minority of participants thought the intervention was too long. The mean and median length of the couple-based interventions was two hours (Std Dev: 25 min).

At both follow-up assessments, we privately asked each member of the couple whether participating in the study "caused any problems or conflicts in your relationship with your main partner?" Analysis of the 950 responses revealed no reported relationship problems or conflicts among individuals who participated in the couple-based HIV-CT. Two male participants assigned to the standard NIDA intervention reported relationship problems stemming from their participation in the study. One complained that his partner had not been truthful about her test results at post-test follow-up. The other reported that his partner became more insistent that he curtail his drug use practices and sexual activities with other partners.

Discussion

The Harlem River Couples Project was the first randomized trial to demonstrate the risk reduction effectiveness of a couple-based HIV counseling and testing intervention among U.S. drug-involved heterosexual couples. The intervention consisted of pre- and post-test counseling visits. The pre-test counseling session, which lasted on average two hours, was administered to individual couples and involved delivery of informational content tailored to each couple's risk profile, stage of behavior change and dyadic HIV serostatus, as well as interactive exercises designed to address community and gender norms and improve couples' communication skills. The pre-test session concluded with individual HIV and hepatitis testing and prevention counseling addressing risk with secondary partners. The post-test session, delivered to individuals one to two weeks after pre-test, consisted of informing clients of their HIV/HBV/HCV test results and reviewing progress and addressing problems related to their personalized action plans from the pre-test session. The randomized trial demonstrated the feasibility and effectiveness of conducting HIV

counseling and testing with U.S. drug-involved heterosexual couples. Perceptions of the intervention were positive among both clients and counselors. The two counselors indicated that the various components of the intervention flowed well and that they encountered no major psychological or other adverse events during intervention delivery.

Delivery and evaluation of a couple-based HIV counseling and testing intervention was not without limitations. Although couples were not directly paid to attend the HIV counseling and testing sessions, they were compensated for each assessment visit (baseline, three-months and nine-months post-intervention) and willingness to participate in the intervention was a criterion to enroll in the study. Thus, we do not know whether couples would voluntarily attend couple-based HIV counseling and testing as an alternative to individual HIV-CT outside of a research context and in the absence of any monetary incentive. The mean age of women enrolled in the study was 38.4 years, and only 10% of the sample was younger than 25 years. The older age of the sample is typical for HIV prevention studies involving drug users (Semaan et al., 2002), but it is not clear whether couple-based HIV-CT interventions would be acceptable and effective among younger women and couples. Another potential source of bias is the exclusion of women who self-reported feeling uncomfortable or threatened participating in a couple-based HIV prevention intervention. This exclusion criterion was implemented for ethical reasons but also because the intervention was not designed to address the needs of more volatile and violent relationships. Post-enrollment, participants who appeared intoxicated or high during a study visit were rescheduled, although this occurrence was rare. Counselors were also trained to recognize potentially abusive situations and how to handle them using conflict resolution tactics. These factors might explain the low prevalence of self-reported couple discord and conflict stemming from participation in the intervention.

The HIV counseling and testing mode of intervention delivery, although brief, has several important advantages over interventions involving multiple sessions, particularly for illicit drug users. HIV-CT is an existing health service that is already accessible and utilized by members of communities characterized by high HIV incidence and prevalence. Moreover, the often chaotic and transient lives of drug users (especially those who are out-of-treatment) often preclude attendance at multiple intervention sessions over many weeks or months. By contrast, HIV-CT consists of a single pre-test and testing session followed by a single post-test session. Participation is often initiated by clients seeking testing who are motivated to learn their HIV status. Further, a recent meta-analysis found that brief HIV prevention interventions were as effective as multi-session interventions for drug-users (Meader et al., 2010). CDC guidelines recommend recurrent HIV counseling and testing at least annually for persons in high-risk categories (Branson et al., 2006), and the intervention therefore has the potential for repeated delivery and sustained risk reduction over time.

Although the intervention was not tailored to any specific cultural, racial or ethnic group, the content and delivery of the intervention was community-focused (i.e., included community-relevant information and exemplars) and counselors were experienced and sensitive to racial/ethnic diversity among the clients. Indeed, as with most interventionist-lead programs, the attributes of the counselors were a key factor in the success of the couple-based approach. Both counselors were bilingual and had over a decade experience administering

HIV prevention interventions and other related health and social services educational and counseling programs within the community. At minimum, interventionists conducting the couple-based HIV-CT intervention should have formal training and at least five years of experience counseling clients dealing with issues of poverty, racial discrimination, stigma, substance use disorders, injection drug use, intimate partner violence and history of abuse, HIV/STI testing, HIV/AIDS and hepatitis infections, partner notification, sexual risk behaviors, and treatment and social services referrals.

The intervention was theory-based, with content tailored to community norms, as well as each couple's risk profile, stage of readiness for behavior change, and dyadic HIV serostatus. The intervention emphasized and reinforced relationship strengths with positive non-judgmental message framing, and interactive content delivery. Participant's life experiences, opinions, perspectives, and concerns were elicited and integrated into structured discussions. The couple-based HIV-CT also offers advantages to people at high risk for HIV. In light of high HIV transmission rates in heterosexual, steady relationships, the dyad remains an important context for implementation of risk reduction.

Conclusions

A theory-guided, brief, couple-based HIV-CT intervention specifically tailored to dyadic risk addresses an important need in HIV prevention research. African-American and Latina drug-involved woman continue to be identified as one of the most vulnerable groups for HIV transmission. The brevity of a 2-session intervention responds to the high attrition and cost challenges of existing multisession HIV prevention interventions. This is particularly salient when targeting populations that may have significant challenges to attending multisession interventions. The couple-based HIV-CT intervention acknowledges and leverages the fact that HIV risk behaviors are dyadic, gender-based, and occur within the context of intimate relationship. By addressing important relationship factors, gender norms, communication dynamics, and providing associated skills-building, the intervention has the potential to more effectively impact sexual decision-making and reduce HIV risk behaviors among drug-involved urban woman. This couple based HIV-CT intervention also has the potential to target specific risk behaviors among other high-risk groups in diverse cultural contexts. Our study demonstrates the feasibility and effectiveness of couple-based HIV-CT intervention designed to address both drug-related and sexual risk behaviors among substance using heterosexual couples in the U. S. in an urban setting.

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Table 1**List of couple-based HIV counseling and testing intervention components**

Pre-Test Joint Couples Session	
1	Introduction
2	Dyadic Risk Assessment
3	Basic Information about HIV/HBV/HCV/STDs
4	Couple's Risk Profile and Risk Reduction Options
5	Couple's Risk Reduction Components
5.1.1	HIV and Hepatitis Regular Testing (P/C/R)
5.1.2	HIV and Hepatitis Regular Testing (A/M)
5.2.1	Condom Use to Prevent HIV/STIs (P/C/R)
5.2.2	Condom Use to Prevent HIV/STIs (A/M)
5.3	Anal Sex and HIV/STI Risk
5.4.1	Safe Injection Practices (P/C/R)
5.4.2	Safe Injection Practices (A/M)
5.5	Safe Sniffing Practices
5.6	The 8-Step TLC (Testing/Lack of outside risk/Condom-free) Option
5.7	Sexual Risk Reduction when Trying to Conceive
5.8.1	Adherence to HIV Treatment (P/C/R)
5.8.2	Adherence to HIV Treatment (A/M)
5.9	Hepatitis C and B Treatment
5.10	Benefits of Drug Treatment
6	Subjective Norms & Communication Skills
7	Action Plan Review
8	HIV/HBV/HCV Testing Part I: Pre-Test Information
Pre-Test Individual Sessions	
9	HIV/HBV/HCV Testing Part II: Sample Collection
10	Risk Reduction with Secondary Partners
Post-Test Counseling Individual Session	
11	HIV/HBV/HCV Testing Part III: Post-Test Counseling

Note. P=Pre-contemplation; C=Contemplation; R=Ready for Action; A=Action; M=Maintenance (stages of readiness behavior change)