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Couples-focused prevention program to reduce HIV risk among transgender women and their primary male partners: Feasibility and promise of the Couples HIV Intervention Program

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Abstract

HIV risk among transgender women has been attributed to condomless sex with primary male partners. This study pilot tested a couples-focused HIV intervention program for transgender women and their primary male partners. We analyzed data from 56 transgender women and their male partners ($n = 112$ participants) who were randomized as a couple to one of two groups. Participants in the intervention group (27 couples) received 3 counseling sessions: 2 couples-focused sessions, which discussed relationship dynamics, communication, and HIV risk, and 1 individual-focused session on HIV prevention concerns. Participants in the control group (29 couples) received 1 session on general HIV prevention information delivered to both partners together, which was identical to the first session of the first session of the intervention group. At 3-month follow-up, participants in the intervention reported lower odds of condomless sex with primary partners (OR = 0.5, 95% CI: 0.3–1.0), reduced odds of engaging in sex with a casual partner (OR = 0.3, 95% CI: 0.1–1.0), and reduction in the number of casual partners ($B = -1.45$, $SE = 0.4$) compared with the control group. Findings provide support for the feasibility and promise of a couples-focused HIV prevention intervention for transgender women and their primary male partners.

INTRODUCTION

Transgender women are among the populations at highest risk for HIV infection in the United States and in many international settings.^{1–3} A meta-analysis of HIV testing studies

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COMPLIANCE WITH ETHICAL STANDARDS

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

conducted with transgender women in the United States estimated 28% HIV seroprevalence,¹ and a meta-analysis of studies conducted internationally with transgender women estimated 19% HIV seroprevalence.³ HIV infection in transgender women has frequently been attributed to condomless sex with a primary male partner – i.e., a man with whom the transgender woman considers herself in a committed relationship.^{4,5,6} Emerging studies have identified men who have sex with transgender women as an HIV risk group.⁷ In previous research, primary male partners of transgender women also reported engaging in sexual behavior with cisgender women and men, and this group may thus reside at a crossroad for HIV transmission across diverse populations.^{8,9} There are no reliable estimates of the size of these populations, though these are likely to be small relative to the national population and therefore hard to reach.^{10,11}

Primary partnerships – defined in this study as a relationship in which two people report being committed to one another above all others and have sex with each other – are complex contexts for HIV prevention.^{12,13} In this relationship context, primary partners may view condomless sex as an expression of intimacy and trust, and in contrast may view condom use as an indication of mistrust and a barrier to the full expression of commitment.¹⁴ Moreover, partners in primary partnerships may perceive themselves to have low risk for HIV and other sexually transmitted infections, especially if they believe themselves to be in a mutually monogamous partnership.¹² Risk for HIV and other sexually transmitted infections persists, however, if one or both partners has sex outside of the relationship with a partner of positive or unknown status, or if one or both partners has an undiagnosed and untreated infection.¹⁵ Additionally, couples may not agree about whether they are in an open or monogamous sexual agreement. Sexual agreements are described as the decisions couples make about whether they allow sex with outside partners and the sexual behaviors they engage in together with the overall aim of minimizing HIV risk;¹⁶ however, evidence illustrates that up to 45% of transgender women and their male partners report discrepant sexual agreements.¹⁷

Couples-focused HIV prevention programs seek to reduce HIV risk for individuals in the context of a primary partnership.¹⁸ These programs differ from individual-focused HIV prevention interventions by focusing on the relationship context, and by acknowledging the partnership as the unit for intervention and behavior change. In addition to reducing condomless sex among primary partners, couples-focused HIV prevention programs may also aim to promote partner communication about safer sex and align partners' agreements about sex outside of the relationship. There is a growing body of research supporting feasibility, acceptability, and effects of couples-focused HIV prevention programs in heterosexual and male same-sex partnerships.^{18,19} A systematic review of couples-focus HIV prevention programs identified common conceptual themes across effective studies including: improving communication between partners; addressing issues of intimacy and trust; acknowledging gender norms and roles between partners such as patterns of decision making and norms about sexual activity; and facilitating safer sex and condom use between partners.¹⁷

This study represents an initial step in establishing the feasibility and potential promise of conducting a couples-based behavioral risk reduction intervention for transgender women

and their male partners in reducing HIV risk behavior. We adapted Project CONNECT for use with this population. Project CONNECT is an empirically supported couples-focused HIV prevention program developed for heterosexual women and their male primary partners,²⁰ and has also been adapted for methamphetamine-using same-sex male couples.²¹ Guided by the relationship-oriented ecological perspective,²² Project CONNECT brings partners together to consider how HIV risk may operate in the context of complex relationship issues (e.g., love, intimacy, trust) and partner communication dynamics.²² A notable feature of this intervention is the focus on partners working together to reduce their own and each other's HIV risk and to promote the well-being of the partnership.²² Furthermore, Project CONNECT places a strong emphasis on the importance of multiple levels of influence on couples HIV risk behaviors, which are inclusive of couples' interactions (i.e., power imbalances, trust), their immediate social context (i.e., socioeconomic status, access to services), as well as how broader cultural values and beliefs (e.g., gender norms) impact these behaviors.²²

The aim of this study was to adapt Project CONNECT and examine the feasibility and promise of this couples-based HIV prevention program for transgender women and their male primary partners. We were specifically interested in exploring preliminary effects of the intervention on sexual behaviors within the partnership and with outside partners

METHODS

This pilot study involved a randomized controlled trial of a couples-focused intervention to reduce HIV risk behavior among transgender women and their primary male partners, entitled CHIP (Couples HIV Intervention Program). The study protocol was implemented from June 2013 to October 2014 in San Francisco and Oakland, CA.

Intervention

CHIP was adapted from Project CONNECT,²⁰ a couples-focused counseling program designed to be delivered in three to five sessions to improve relationship communication, partner interpersonal dynamics, and HIV risk reduction behaviors. Core elements of Project CONNECT include the following: emphasizing the relationship, rather than the individual exclusively, as the unit of intervention; addressing trust and commitment within the relationship; emphasizing communication between partners; providing realistic scenarios to model communication and sexual decision making. Adaptations to the Project CONNECT framework were made based on formative research with transgender women and male partners of transgender women, in which we used focus group discussions with each subgroup separately to elicit feedback and recommendations to improve the fit between the intervention framework and the study populations. Details about the adaptation process will be described in a separate manuscript. In summary, we learned about language, terminology, and role-play scenarios that were deemed appropriate to the study population – e.g., including an additional focus on communication and sexual agreements related to having a monogamous or open relationship. We learned about the social contexts that shaped their relationships, such as stigma toward these partnerships (especially for male partners), opportunities for social support for these partnerships, and perceived gender roles for

transgender women and male partners that might influence communication and sexual dynamics. We also learned about the importance of separating partners in individual counseling sessions to establish personal understandings about their own individual risk factors, in addition to bringing couples together to discuss their partner-level HIV risk. Based on our understanding of participants' desire for fewer sessions and the possible challenges in retention, we opted to deliver the intervention content across three sessions total.

CHIP involved three 1- to 1.5-hour counseling sessions (see Figure 1). In the first session, partners met together with a trained research assistant who provided them with basic informational counseling on sexual transmission of HIV and other sexually transmitted infections, condom use, and HIV testing - including the importance of testing at least every 6 months for individuals having sex with an HIV-positive or status-unknown partner. As "homework", participants were asked to consider their own and their partner's unique HIV prevention needs and challenges for discussion during the next session. In the second session, each partner met individually with the research assistant to discuss the following topics: understanding HIV risk in serodiscordant versus concordant (HIV-negative and HIV-positive) primary partnerships; personal definitions of relationship issues including trust, commitment, communication, and monogamy; the role of each of the aforementioned factors in influencing HIV risk among primary partners; personal understandings about the reasons for high prevalence of HIV in the transgender community; personal experiences of stigma related to gender identity (for transgender women) or sexuality (for male partners) and the consequences of stigma on HIV risk behavior. As homework, participants were asked to consider how social and relationship dynamics influence their abilities to promote their sexual health and to communicate effectively about HIV and other health issues, which would be considered in the next session. In the third session, partners met together with the research assistant to discuss the following topics: effective partner communication, active listening, and conflict resolution; enhancing mutual support among partners; identifying personal and couple-level HIV prevention goals. Each of these topics included role play scenarios, based on topics identified in the prior sessions, for partners to practice new skills. As a final homework assignment, participants were asked to implement the skills provided during the role play scenarios.

In the control condition, partners completed a single session on general HIV prevention information delivered to both partners together. This content of this single session was identical to the content delivered during the first session of the intervention group, but control participants were not given homework to consider for subsequent sessions. We considered providing participants in the control condition with minimal intervention content (e.g., basic individual-level HIV prevention information), but given the known levels of risk within these dyads and the exploratory nature of the study decided to provide all participants with a single session of couples HIV prevention information.

Participants

Participants were recruited over a 13-month period using targeted sampling methods at venues where members of the community were known to frequent (e.g., community

organizations, bars, nightclubs, beauty salons) and through referrals from community members. Recruitment flyers were disseminated with information about the study, including contact details for initial phone screening. To be eligible, participants must have met the following inclusion criteria: age 18 or older; identify as either a transgender woman or cisgender man; live or work in the San Francisco bay area; be in a primary partnership with a transgender woman (if the participant identified as a cisgender man) or with a cisgender man (if the participant identified as a transgender woman); able to speak English; do not intend to relocate during the next 3 months. During screening, we inquired whether individuals felt coerced by their partner to participate in the study and planned to exclude any participants who reported feeling coerced; no participants reported coercion. Owing to the nature of the intervention program, participants were eligible only if their primary partner (screened separately) also met inclusion criteria and agreed to participate in the study. If both partners satisfied these criteria, they were scheduled for an appointment to meet with the study intake coordinator.

Procedures

Partners met together with a research assistant at a private office space where they were given an overview of the study. They were then each moved into private rooms where they individually provided informed consent, completed a 30 minute baseline assessment questionnaire, and provided contact information. Next, they were brought together in the same room and randomized to the intervention or control group by selecting a sealed opaque envelope that contained the assigned condition, which was recorded by the research assistant. Couples completed the first counseling session immediately after randomization. Those in the intervention group were scheduled for subsequent weekly counseling sessions, and received reminder phone calls the day prior to the scheduled session. All participants were scheduled in advance for an individual 3-month follow-up assessment, and reminder phone calls were given three days and one day in advance. Participants individually received \$30 for completing the intake and counseling session 1, \$30 for each subsequent counseling session, and \$40 for completing the 3-month follow-up. The Institutional Review Boards from Brown University and Public Health Institute approved the protocols, materials, and information used in this study.

Figure 2 presents the study flowchart. A total of 120 participants (60 couples total) attended the initial appointment, completed the baseline assessment, and randomly allocated to the CHIP intervention (30 couples) or control (30 couples). Four couples discontinued the intervention and were omitted from analysis: 3 in the intervention group (1 was determined to not be in a committed partnership and 2 withdrew from the study) and 1 withdrew from the control condition; we lack specific information about the reasons for withdrawal from the study. Of those who completed the baseline and attended the first session ($n=54$ individuals; 27 couples), 96.3% ($n = 52$ individuals; 26 couples) attended the second individual counseling session, and 92.3% ($n = 50$ individuals; 25 couples) attended the final couples counseling session. Of the 112 participants (56 couples total) who were included in analysis, 24 participants (12 couples) and 3 additional male partners (26.9%) were lost by the 3-month follow up. Reasons for study attrition included not being able to be contacted (12 couples), two male partners went to jail, and one male partner moved across the country.

Measures

Sociodemographic characteristics—Participants self-reported their age, race/ethnicity, annual income, educational level, HIV status, whether they lived together and relationship length.

Sexual risk behavior—Sexual behavior with primary partners in the previous three months was assessed using six items. Three items assessed whether or not the participant engaged in insertive and receptive anal sex or vaginal sex with their main partner (“yes or no” response). Three subsequent items assessed how often condoms were used during each of these sexual acts. Couples were classified as “engaging in condomless sex” if either partner reported anal or vaginal sex and condoms were not used every time. Couple-level agreement with regard to the occurrence of sexual activity was high (95.6%). Results for condom use were similar, with partners agreeing in 80.8% of the couples. Participants were also asked to report whether they had had any outside casual sex partners in the prior 3 months (“yes or no” response) and the number of outside sexual partners during that time period.

Drug use—Participants were also asked if they had used any non-marijuana illicit drug use in the past 3 months (“yes” or “no” response).

Sexual agreement types—Perceived sexual arrangement was assessed using a single item, which asked participants to indicate “How you and your partner handle sex outside of your relationship,” and any agreements about sex outside of a primary relationship (i.e., “neither of us has sex with others”; “we can have sex with outside partners, but with some conditions or restrictions”; “we can have sex with outside partners, without any conditions or restrictions,” or “we do not have any agreements”). We classified couples into one of three categories based upon both members’ description of their sexual agreement. Couples were classified as monogamous ($n = 23$) if both members of the couple indicated “neither of us has sex with outside partners.” Couples were categorized as open ($n = 2$) if both members of the couple indicated “we can have sex with outside partners, but with some conditions or restrictions” or “we can have sex with outside partners, without any conditions or restrictions.” Couples were categorized as discrepant if one member indicated the relationship was open ($n = 18$) or didn’t have an agreement ($n = 10$) and the other indicated that it was monogamous. In a small number of dyads ($n = 3$) one member indicated the relationship was open and the other that they didn’t have an agreement. This combination was included in the discrepant category as it represents a difference in partners being on the same page in terms of their sexual agreement. Given the few couples in a mutually open sexual agreement, we created a dichotomous variable: 1 = mutually monogamous or open and 0 = discrepant.

Trust—Participants indicated their level of trust in their primary relationship using a modified 8-item Dyadic Trust scale.²³ Items included, “My partner is perfectly honest and trustful with me” and “I can count on my partner to help me.” Participants indicated their agreement on a 5-point Likert scale (1 = *Strongly disagree* to 5 = *Strongly agree*). Items were coded such that higher scores indicated greater trust (for transgender women, baseline

$\alpha = 0.83$ and follow-up $\alpha = 0.78$; for male partners, baseline $\alpha = 0.80$ and follow-up $\alpha = 0.82$). Total scores ranged from 3 to 33.

Gender norms—Participants completed 7-item gender norms scale.²⁴ Items included, “A woman and not her man should do the housework” and “If a man and woman are arguing, it is important for her to ‘give in’, so that they will stop arguing” (1 = *Strongly disagree* to 5 = *Strongly agree*). Items were coded such that higher scores indicated greater endorsement of traditional gender norms (for transgender women, baseline $\alpha = 0.66$ and follow-up $\alpha = 0.71$; for male partners, baseline $\alpha = 0.72$ and follow-up $\alpha = 0.84$). Total scores ranged from 1 to 27.

Condom self-efficacy—Participants completed a 7-item condom self-efficacy scale.²⁵ Items included, “I feel confident in my ability to put a condom on my partner or myself” and “I feel confident that I would stop to put a condom on myself or my partner even in the heat of the moment” (1 = *Strongly disagree* to 5 = *Strongly agree*). Items were coded such that higher scores indicated greater self-efficacy for condom use (for transgender women, baseline $\alpha = 0.89$ and follow-up $\alpha = 0.91$; for male partners, baseline $\alpha = 0.94$ and follow-up $\alpha = 0.92$). Total scores ranged from 6 to 30.

Sexual communication—Participants completed a modified 5-item sexual communication scale.²⁶ Participants were asked to indicate how frequently they engaged in communication about their sexual health (i.e., “discussed how to use condoms,” “discussed how to prevent AIDS with my primary partner,” “discussed HIV testing with my partner,” “discussed how to prevent STIs with my primary partner,” “discussed how to improve sexual pleasure with my primary partner” (1 = *Never*; 2 = *Sometimes*; 3 = *Often*; 4 = *A lot*). The scale demonstrated good psychometric properties (for transgender women, baseline $\alpha = 0.91$ and follow-up $\alpha = 0.88$; for male partners, baseline $\alpha = 0.92$ and follow-up $\alpha = 0.90$). Total scores ranged from 2 to 20.

Statistical Analyses

For the preliminary analyses, we compared participants in the intervention group with those in the control group on several demographic, sexual health, and psychosocial variables to determine whether randomization was successful in equating the groups before the intervention. Statistical testing for differences between groups on categorical variables, such as income and educational level, was done using chi-square test, and comparisons of continuous variables were performed using the Wilcoxon rank-sum test.

Statistical analyses relied primarily on generalized linear mixed models (GLMM) which can account for correlations which arise from repeated measures from a participant (i.e., the level 2 unit), and the correlations between partners who participated in the intervention (i.e., the level 3 unit) and measures which may involve behaviors between two partners. Discrepant reports between two partners on conjoint behaviors (e.g., condomless sex together) can be handled and treated in the error terms in GLMM, altogether providing a better approach to handling uncertainty to discrepant responses compare to alternatives (e.g., forcing one partner into a high risk group) that will not result in underestimated standard

errors. We used appropriate link functions based on the distribution of the outcome variable. For the number of casual partners, we fit GLMM with zero-inflated Poisson distributions and maximum likelihood estimation to test these effects on the count outcome. For secondary psychosocial outcomes, we used an identity link function for continuous outcomes and a logic link for binary outcomes. Random effects implemented a random intercept and slope for level 2 (participant) and level 3 (couple) units and all models statistically adjusted for gender, income, HIV status, any non-marijuana illicit drug use in the past 3 months, and the baseline level of the outcome measure. To account for missing data, all analyses were performed using the intention-to-treat-last observation forward approach.²⁷ Thus, the interpretation of the coefficient outcomes represents the overall difference in the outcome between the intervention and control groups, controlling for the baseline value and covariates. GLMM effect estimates represent odds ratios estimated for logistic regression for binary outcomes, rate ratios for zero-inflated Poisson regressions for count outcomes, and mean differences estimated by linear regression for continuous variables. All analyses were conducted in SPSS version 22.

RESULTS

Sample Description

Of the 112 participants (56 couples total) included in analyses, the average length of partnership ranged from 2 to 228 months ($M = 50.79$, $SD = 54.17$) and 58.9% ($n = 66$) lived together. The average age of participants was 43.65 ($SD = 10.57$). In total, 31.3% ($n = 35$) of participants self-identified as HIV-infected, 58% ($n = 65$) HIV-uninfected, and 10.8% ($n = 12$) unknown or refused. The majority of the sample self-identified as a racial/ethnic minority: 45.5% ($n = 51$) Black, 14.3% ($n = 16$) Hispanic, 14.3% ($n = 16$) Mixed Race, 8% ($n = 9$) Asian or Pacific Islander, 1.8% ($n = 2$) American Indian or Alaskan Native, and 16.1% ($n = 18$) White. Approximately half of the sample ($n = 57$) earned a high school degree or less and 72.3% ($n = 81$) earned less than \$1,000 monthly.

Table 2 presents baseline characteristics of the participants by study condition. There were no statistically significant differences between groups with respect to demographics, sexual health and psychosocial variables. However, a statistically significant baseline difference was noted in income. Specifically, both transgender women and their male partners in the intervention group reported significantly lower income compared to the control condition. Consequently, we statistically adjusted for income in all subsequent analyses.

When participants who completed the follow-up appointment ($n = 85$ participants) were compared to those who were lost to follow-up ($n = 27$ participants), no statistically significant differences were found between dropouts and those who completed both baseline and follow-up assessments on condition, demographics, sexual health, and psychosocial variables. However, couples who lived together at the time of their baseline assessment were significantly more likely to complete the 3-month follow-up assessment (82.7%) compared to those who didn't live together (51.4%), $\chi^2(2) = 12.62$, $p < 0.01$. Furthermore, there were no statistically significant differences between those who did not complete the follow-up appointment by study condition on any demographic, sexual health, or psychosocial variable.

Intervention Analyses

At baseline, 24/112 (21.4%) of the sample reported engaging in condomless sex with their primary partners; this proportion decreased to 18/112 (16.1%) at the 3-month post-intervention follow up assessment across both conditions. At baseline, 23/56 (41.1%) of couples reported a mutually monogamous sexual agreement, 2/56 (3.6%) of couples reported a mutually open sexual agreement, 31/56 (55.4%) reported a discrepant agreement. At the 3-month post-intervention follow up assessment, 29/56 (51.8 %) of couples reported a mutually monogamous sexual agreement, 11/42 (19.6 %) of couples reported a mutually open sexual agreement, and 16/56 (28.6 %) reported a discrepant agreement across both conditions. At baseline, 29/112 (25.9%) of the participants reported having sex with a casual partner compared to 28/112 (25.0%) at the 3-month post-intervention follow up assessment. Overall, there were no significant differences in the odds of reporting condomless sex with a primary partner or the odds of participants who reported any casual partners from the baseline to follow-up assessment across both conditions. When we stratified by intervention conditions, there were significant bivariate differences in the intervention group such that there were significant reductions in the odds of participants who engaged in condomless sex with a primary partner and reported sex with a casual partner from baseline to follow-up. Additionally, we found a significant decrease in the proportion of casual partners from baseline to follow-up among the participants in the intervention group. By contrast, we found no significant bivariate differences in the odds of participants who reported engaging in condomless sex with a primary partner or reported sex with a casual partners from baseline to the follow-up among those who were assigned to the control condition; however, there was a marginally significant trend demonstrating a decrease in the proportion odds of causal partners reported from baseline to follow-up among those in the control group ($p = 0.052$).

Table 3 presents unadjusted and adjusted general linear mixed models predicting the sexual risk outcomes, as well as effect size estimates. There was a significant decrease in the odds of engaging in condomless sex with primary partners among the couples in the intervention group compared to the control group (AOR = 0.5, 95% CI: 0.3–1.0, $p < 0.05$). With respect to sexual agreements, there were no significant differences in couples reporting a mutually open or monogamous sexual agreement compared to a discrepant sexual agreement between the conditions. Participants in the intervention condition had a reduced odds of reporting casual partners compared to those in the control condition (AOR = 0.3, 95% CI: 0.1–1.0, $p < 0.05$). Furthermore, participants in the intervention condition had a reduced number of casual sex partners compared with those in the control condition ($B = -1.5$, $SE = 0.4$, $p < 0.01$) at 3-month follow-up. Specifically, the number of casual partners was lower in the intervention group ($M = 0.2$, $SE = 0.1$) compared to the control group ($M = 0.6$, $SE = 0.1$) at 3-month follow-up. Notably, there was a significant difference in number of causal partners by gender. Due to limited power, we fit GLMM models stratified by gender to estimate the effects of the intervention on number of casual partners, rather than test the interaction of gender x intervention group on casual partners. Transgender women in the intervention group ($M = 0.04$, $SE = 0.03$) had a significantly lower number of casual sex partners than those in the control group ($M = 0.5$, $SE = 0.2$) at the 3-month follow-up ($B = -3.5$, $SE = 1.0$, $p < 0.01$). No differences were observed among male partners in the number of casual sex

partners at the 3-month follow-up ($B = -1.0$, $SE = 0.5$, $p = 0.06$). Additionally, there were no differences between conditions in any of the secondary psychosocial outcomes (i.e., trust, gender norms, condom self-efficacy, or sexual communication).

DISCUSSION

This initial evaluation of CHIP suggests feasibility and promise of a couples-focused HIV prevention program for transgender women and their male primary partners. At 3-month follow-up, we found that both transgender women and cisgender male participants in the intervention group reported significant reductions in the odds of having condomless sex with their primary partners compared with those in the control, and that transgender women in the intervention group reported significant reductions in their number of casual partners (i.e., those outside of the primary relationship). While our effect sizes were smaller than Project CONNECT,¹⁸ these data are a promising indication that the CHIP intervention facilitated couples' communication about HIV risk reduction.

CHIP was modified from Project CONNECT, an efficacious multi-session couples-focused HIV prevention program for heterosexual women and their cisgender male primary partners.¹⁸ We reduced the number of repeated sessions from five to three sessions total, based on our understanding of the challenges in retaining this population in a multi-session intervention. CHIP also addressed HIV risk with partners outside of the primary relationship, which was not an explicit feature of Project CONNECT. Additionally, CHIP addressed how relationship dynamics are affected by stigma that transgender women and their primary male partners experience as members of a dyad or as individuals. Whereas the original evaluation of Project CONNECT compared the couple-session intervention with both a woman-alone comparison group and an education comparison group, the control group for this study involved a single couples-focused HIV prevention session.

The intervention and evaluation procedures were shown to be feasible, and areas of improvement for future research have been identified. Once accounting for excluded participants, 89% of the sample completed all intervention sessions and 73% completed the final assessment. Twelve couples total were lost from contact and were unable to be reached via phone; future research with these populations will benefit by using multiple strategies (phone, text, email) for maintaining participant contact. Other reasons for attrition included incarceration or movement away from the study site, which are difficult issues to anticipate when working with community samples. Indeed, offering more sessions would provide couples with an opportunity for deeper engagement in core topics, and could also provide additional time to explore the expanding suite of HIV prevention modalities including biomedical intervention (such as pre-exposure prophylaxis) as well as treatment strategies to improve clinical outcomes for HIV-positive participants. Effects of the intervention on reduced condomless sex with primary partners are particularly noteworthy given the challenges, described previously, in promoting condom use in the context of primary relationships.^{4,5}

Consistent with Project CONNECT,²⁰ this intervention was developed to help participants consider how relationship dynamics such as trust and intimacy can be enhanced through

communication and increased perceptions of safety, and that these relationship motives are not inconsistent with promoting condom use among partners. Building on these principles, we asked program participants to consider some of the unique factors that might contribute to HIV transmission and challenge condom use among transgender women and their male primary partners, such as relationship stigma, gender roles, and outside partnerships, and we provided opportunities for partners to explore strategies for supporting each other's HIV prevention goals. Given the absence of interventions to support healthy relationships among these dyads, this program also provided an opportunity for partners to feel affirmed and legitimized, in addition to addressing HIV prevention.¹⁸

Limitations of this study must be noted. Because the study used a short-term follow-up assessment, future research is needed to examine whether the intervention had longer-term effects on behavior. Due to ethical considerations we did not use an attention-matched control group, and effects might thereby be confounded with time of intervention exposure. Participant HIV status was determined based on self-report without biological confirmation. We did not collect systematic screening information from all contacts encountered in field settings (e.g., bars, nightclubs, community organizations), and thus do not have comprehensive information about total numbers screened and reasons for exclusion from enrollment. Also, due to limited sample size, we lacked the ability to examine behavioral effects by couple serostatus (HIV-positive seroconcordance, HIV-negative seroconcordance, HIV discordance) and we did not assess viral suppression status of HIV-infected partners, which are both important parameters that determine the risk for HIV transmission and need for condom use among primary partners. While the last-observation-carry-forward (LOCF) method is a common approach for handling missing data, our analyses may have produced biased standard errors compared to other imputation methods.²⁸ We also lacked detailed measures about drug and alcohol use, couples-focused stigma, sexual power, and intimate partner violence, which should be addressed in a more nuanced manner in future couples-focused intervention research with these populations. Future research should be prepared to address or provide referrals for these issues – particularly substance use and intimate partner violence. In an effort to minimize participant burden, we did not assess theoretical components of the intervention such as global relationship functioning and communication. Thus, the intervention may have had a positive impact on relationship satisfaction and effective communication strategies (i.e., open communication, joint problem solving), which we did not capture in our assessments. The geographic context in which the program was delivered (i.e., the San Francisco Bay area) must also be considered, and both the ability to deliver this program and intervention results might not be generalizable in other settings where members of these groups might experience even more discomfort and stigma. Finally, due to the tightly knit community in this geographic location, contamination between intervention and control groups may have occurred.

In summary, this research supports the feasibility and preliminary effects of a couples-focused HIV intervention, with significant effects observed on condomless sex among transgender women and their male primary partners. Thus, the intervention may have enhanced relationship motivations for engaging in safer sex practices, such as building, protecting, and strengthening the relationship, in order to prevent HIV and other STIs. Taken together, these findings contribute to the arsenal of HIV prevention strategies for couples,

and are the first known findings showing effects in male partners of transgender women who are difficult-to-reach and in need of enhanced access to the HIV continuum of care.⁹ More work is needed to explore relationship dynamics and HIV risk among other gender types of non-conforming couples.

Findings from this couples-focused pilot intervention might have relevance for the expanding suite of efficacious biomedical HIV prevention strategies. In 2012, the World Health Organization released guidelines for couples HIV testing and counseling (CHTC), which includes the provisions of antiretroviral therapy (ART) treatment and prevention.²⁹ Given the success of biomedical HIV prevention strategies, such as pre-exposure prophylaxis and early treatment,^{30,31} the incorporation of couples-based intervention into CHTC and the provision of biomedical strategies has the potential to make a powerful and sustained impact on the sexual health of transgender women and their cisgender male partners. Future couples-focused research is warranted to examine the applicability and acceptability of these biomedical strategies in the context of partners within a committed relationship,³² and the role of partners in supporting use of CHTC and biomedical strategies among transgender women and their male primary partners. As previous research has supported the role of primary partners and significant others on health service utilization and compliance with treatment recommendations,^{33–36} future work with gender and sexual minority populations is needed to investigate the protective health effects of being in a couple with regard to HIV biomedical interventions.

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Session	Content
1 – Couples counseling	<ul style="list-style-type: none"> • Basic principles of HIV and other sexually transmitted infections • Strategies for HIV prevention, including condom and lubrication demonstration • HIV testing recommendations, and diagnosis of HIV status • Basic individual risk factors for HIV transmission
2 – Individual counseling	<ul style="list-style-type: none"> • HIV in primary partnerships, including role of serodiscordant and seroconcordant positive or negative primary partnerships • Relationship values including trust, commitment, communication, monogamy • Understandings within the relationship about outside partnerships • Personal experiences of stigma including individual-level and couple-level stigma
3 – Couples counseling	<ul style="list-style-type: none"> • Effective partner communication, including role play scenarios • Social support – providing support to one another within the relationship and finding outside sources to support the relationship • Identifying and affirming individual and relationship goals related to HIV prevention

Figure 1.
Theoretical components of the Couples HIV Intervention Program

Figure 2.
Participant flowchart

Table 1

Baseline characteristics of sample by treatment condition (N = 112; 56 couples)

	TW ^a		TW ^a		p-value	Males		Males		p-value
	Intervention (n = 27)	Control (n = 27)	Intervention (n = 29)	Control (n = 29)		Intervention (n = 27)	Control (n = 27)	Intervention (n = 29)	Control (n = 29)	
<i>Age, years (M, SD)</i>	46.22 (7.84)	41.21 (12.10)	41.21 (12.10)	41.21 (12.10)	0.077	45.56 (10.04)	41.62 (11.37)	45.56 (10.04)	41.62 (11.37)	0.187
<i>Relationship length, (M, SD)</i>	48.86 (45.30)	67.96 (53.35)	67.96 (53.35)	67.96 (53.35)	0.158	47.33 (46.28)	72.39 (61.33)	47.33 (46.28)	72.39 (61.33)	0.094
<i>Race (n %)</i>					0.061					0.844
Black	10 (34.5)	15 (55.6)	15 (55.6)	15 (55.6)		13 (44.8)	13 (48.1)	13 (44.8)	13 (48.1)	
Hispanic	4 (13.8)	7 (25.9)	7 (25.9)	7 (25.9)		2 (6.9)	3 (11.1)	2 (6.9)	3 (11.1)	
White	3 (10.3)	2 (7.3)	2 (7.3)	2 (7.3)		8 (27.6)	5 (18.5)	8 (27.6)	5 (18.5)	
Other	12 (41.4)	3 (11.1)	3 (11.1)	3 (11.1)		6 (20.7)	6 (22.2)	6 (20.7)	6 (22.2)	
<i>Education (n, %)</i>										
High School Degree or Less	13 (44.8)	17 (63.0)	17 (63.0)	17 (63.0)	0.174	13 (44.8)	14 (51.9)	13 (44.8)	14 (51.9)	0.599
<i>Monthly Income (n, %)</i>										
Less than \$1,000	16 (59.3)	23 (79.3)	23 (79.3)	23 (79.3)	0.042	17 (63.0)	25 (86.2)	17 (63.0)	25 (86.2)	0.014
<i>Any sex with casual partner (n, %)</i>	4 (27.6)	8 (27.6)	8 (27.6)	8 (27.6)	0.244	7 (25.9)	3 (10.3)	7 (25.9)	3 (10.3)	0.128
<i>Any STI (n, %)</i>	5 (17.2)	5 (18.5)	5 (18.5)	5 (18.5)	0.901	3 (10.3)	3 (11.1)	3 (10.3)	3 (11.1)	0.926
<i>Number of Casual Partners(M, SD)</i>	3.00 (1.83)	1.63 (1.06)	1.63 (1.06)	1.63 (1.06)	0.124	2.43 (4.24)	4.66 (4.62)	2.43 (4.24)	4.66 (4.62)	0.476
<i>Trust (M, SD)</i>	17.69 (5.46)	16.36 (7.01)	16.36 (7.01)	16.36 (7.01)	0.441	17.07 (5.48)	16.83 (4.07)	17.07 (5.48)	16.83 (4.07)	0.849
<i>Condom Self-Efficacy (M, SD)</i>	21.12 (6.19)	21.44 (6.57)	21.44 (6.57)	21.44 (6.57)	0.856	22.78 (7.89)	21.69 (5.68)	22.78 (7.89)	21.69 (5.68)	0.554
<i>Gender Norms (M, SD)</i>	14.65 (5.03)	15.45 (5.08)	15.45 (5.08)	15.45 (5.08)	0.564	16.63 (4.63)	16.66 (5.21)	16.63 (4.63)	16.66 (5.21)	0.985
<i>Sexual Communication(M, SD)</i>	9.23 (3.94)	10.36 (11.30)	10.36 (11.30)	10.36 (11.30)	0.373	10.22 (5.05)	9.35 (4.27)	10.22 (5.05)	9.35 (4.27)	0.485

^aTW=Transgender women

Table 2

Baseline characteristics of couple-level variables by treatment condition (n = 56)

	Intervention (n = 27)	Control (n = 29)	p-value
<i>Cohabitation</i>	18 (62.1)	15 (55.6)	0.621
<i>Couple HIV status</i>			0.405
Discordant	3 (10.3)	7 (25.9)	
Concordant negative	16 (55.2)	10 (37.0)	
Concordant positive	6 (20.7)	6 (22.2)	
One or both refuse/don't know	4 (13.8)	4 (14.8)	
<i>Sexual Agreement</i>			0.617
Open	1 (3.4)	2 (7.4)	
Monogamous	14 (48.3)	10 (37.0)	
Discrepant	14 (48.3)	15 (55.6)	
<i>Condomless anal or vaginal sex with primary partner</i>	13 (44.8)	17 (63.0)	0.174

Table 3

Unadjusted and Adjusted generalized linear mixed model regression estimates of primary outcomes (n=112)

	CAVS with pp ^b			Mutual Agreement ^c			Any Casual Partners			No. Casual Partners		
	OR (95% CI)	AOR (95% CI)		OR (95% CI)	AOR (95% CI)		OR (95% CI)	AOR (95% CI)		B (SE)	B (SE)	
CHIPS vs. Control	0.5 (0.3, 0.8) **	0.5 (0.3, 1.0) *		1.2 (0.6, 2.6)	0.9 (0.3, 2.8)		0.5 (0.2, 1.0) *	0.3 (0.1, 1.0) *		-1.3 (0.3) ***	-1.5 (0.4) **	
Gender ^d		0.9 (0.4, 1.9)			0.8 (0.3, 2.4)			1.4 (0.42, 4.9)			-0.9 (0.3) **	
Baseline Measure		0.7 (0.4, 1.1)			0.0 (0.0, 0.1) **			1.0 (1.0, 3.1) **			0.2 (0.1) **	
Low Income		1.0 (0.3, 2.4)			1.6 (0.4, 5.6)			1.7 (0.4, 7.7)			0.5 (0.1)	
Any Drug Use		1.4 (0.4, 1.9)			1.9 (0.6, 6.6)			1.4 (0.4, 5.4)			-1.4 (0.4) ***	
HIV-positive		1.0 (0.4, 2.4)			0.7 (0.2, 2.2)			0.6 (0.2, 2.3)			-0.8 (0.3) *	
Cohen ^d	-0.38	--		0.10	--		-0.38	--		-0.42	--	

OR=Odds Ratio; AOR=Adjusted Odds Ratio

^aDummy Code 1=Transgender Woman 0=Male^bCondomless Anal or Vaginal Sex with primary partner^cDummy Code 1=Mutual Open or Monogamous Sexual Agreement 0=Discrepant Sexual Agreement^dLow Income = Monthly Income \$1000 or less**
p<0.01;*
p<0.05