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Examining the Efficacy of HIV Risk-Reduction Counseling on the Sexual Risk Behaviors of a National Sample of Drug Abuse Treatment Clients: Analysis of Subgroups

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Abstract

HIV counseling with testing has been part of HIV prevention in the U.S. since the 1980s. Despite the long-standing history of HIV testing with prevention counseling, the CDC released HIV testing recommendations for health care settings contesting benefits of prevention counseling with testing in reducing sexual risk behaviors among HIV-negatives in 2006. Efficacy of brief HIV risk-reduction counseling (RRC) in decreasing sexual risk among subgroups of substance use treatment clients was examined using multisite RCT data. Interaction tests between RRC and subgroups

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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. The Western Institutional Review Board (WIRB) reviewed and approved all procedures related to the parent trial.

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

Compliance with Ethical Standards

Conflict of interest LG, LRM, MRP, CKM, LFH, AD, JC and DJF reported that their respective institutions received grant funds from the study sponsor in support of this study. LG, LRM, AD, and JC reported that their respective institutions received support for travel related to this study. LG and JC reported that they and their respective institutions received funding from other grants from the study sponsor. No other disclosures were reported.

were performed; multivariable regression evaluated the relationship between RRC (with rapid testing) and sex risk. Subgroups were defined by demographics, risk type and level, attitudes/perceptions, and behavioral history. There was an effect ($p < .0028$) of counseling on number of sex partners among some subgroups. Certain subgroups may benefit from HIV RRC; this should be examined in studies with larger sample sizes, designed to assess the specific subgroup(s).

Keywords

HIV; Prevention; Counseling; Substance use; Drug treatment

Introduction

Despite the long-standing history of providing HIV testing in conjunction with prevention counseling, in 2006 the CDC disseminated revised recommendations for HIV testing of adults, adolescents and pregnant women in health care settings (including substance use treatment centers). These recommendations promote routine voluntary HIV screening as part of normal clinical practice and indicate that prevention counseling should not be required in conjunction with diagnostic HIV testing or screening [1]. The recommendation to uncouple HIV testing and prevention counseling was made without the support of any prospective studies evaluating the effect of offering HIV testing without counseling on (1) acceptance of testing and receipt of results and (2) sexual risk behaviors.

Given the role that substance use has played in the spread of HIV [2–6], implementation of HIV testing without risk-reduction counseling in the substance use treatment setting was of particular interest and controversy. It is widely known that injection drug use and sharing of both contaminated syringes and injection paraphernalia helped to fuel the early HIV epidemic [7–13]. Furthermore, there are numerous studies that have shown that both injection drug users and non-injection drug users engage in sexual behaviors that put them at risk for HIV and other sexually transmitted infections (STIs). Despite great strides made in intervening with drug users to decrease injection-related risks, the injection practices and sexual risk behavior of injection drug users and their non-drug-using partners continue to perpetuate the HIV epidemic [13–20]. Substance users enrolled in substance use treatment programs have also demonstrated risky sexual behavior in some studies [21–23].

In response to the CDC's new HIV testing recommendations and lack of strong scientific support for them as well as the need to intensify HIV prevention efforts among substance users, Metsch et al. [24] conducted a randomized, controlled trial, *CTN 0032: HIV Rapid Testing & Counseling in Drug Abuse Treatment Programs in the U.S.* The trial evaluated the more effective strategy (referral for off-site HIV testing, offer of on-site rapid testing with information, or offer of on-site rapid testing with brief counseling) to (1) increase HIV testing acceptance and receipt of results and (2) decrease HIV sexual risk behaviors among individuals receiving substance use treatment within community-based substance use treatment programs in the United States. The CTN 0032 trial was sponsored by the Center for Clinical Trials Network (CCTN) of the National Institute on Drug Abuse (NIDA) and the primary outcome analysis indicated that while there was value in implementing routine rapid

HIV testing in substance use treatment centers, there was no additional benefit (e.g., decrease in sexual risk behaviors) from providing brief HIV risk-reduction counseling. [24] Further, cost-effectiveness analyses demonstrated that the offer of on-site rapid testing with information only increases life expectancy for newly diagnosed HIV-infected individuals at an adequate cost-effectiveness ratio of \$60,300/quality-adjusted life year. The addition of brief risk-reduction counseling increased cost without improving HIV test acceptance or decreasing sexual risk behavior among trial participants [25].

The *National HIV/AIDS Strategy for the U.S.: Updated to 2020* has four primary goals: (1) reducing the number of people who become infected with HIV, (2) increasing access to care and optimizing health outcomes for people living with HIV, (3) reducing HIV-related health disparities and (4) achieving a more coordinated national response to the HIV epidemic. The Updated Strategy recommends “intensifying HIV prevention efforts in communities in which HIV is most heavily concentrated and expanding targeted efforts to prevent HIV infection using a combination of effective, evidence-based approaches.” [26] The U.S. Department of Health and Human Services’ new 10-year goals and objectives for health promotion and disease prevention, Healthy People 2020, also outlines several objectives for HIV testing and prevention, including “increas(ing) the proportion of substance abuse treatment facilities that offer HIV/AIDS education, counseling, and support [27].” While the CTN 0032 primary outcome analyses indicate that offering brief counseling in conjunction with rapid HIV testing did not appreciably reduce sexual risk behavior, these national goals accent the importance of intensifying HIV testing and counseling efforts among substance users, including expanding these services within substance use treatment centers. Further, both behavioral prevention [28] and medical [29–33] research have frequently shown conspicuous subgroup interactions in treatment effect. Therefore, it is important to undertake a more in-depth (albeit exploratory) examination of the efficacy of brief risk-reduction counseling to determine whether there are any subgroups for which brief risk-reduction counseling may be efficacious. If such subgroups exist, a predictive model could be used to target these subgroups in the future for the delivery of brief risk-reduction counseling. Within this context, we conducted secondary CTN 0032 analyses to determine whether delivering brief counseling in conjunction with rapid testing was efficacious in reducing sexual risk behavior among any subgroups of substance users.

Through conducting a series of post hoc analyses on data collected from the CTN 0032 trial, this paper seeks to answer the following question: Does brief HIV risk-reduction counseling decrease sexual risk behavior among different subgroups of substance use treatment clients? Subgroup analyses evaluated three dependent variables associated with sexual risk for HIV acquisition where “sex” is defined as anal and vaginal sex and “risk” is defined as sex without a condom: (1) number of risky sex acts with any (primary and non-primary) partners, (2) number of risky sex acts with non-primary partners, and (3) number of sex partners. Independent variables included socio-demographic, psychosocial and behavioral characteristics.

Methods

Research Design and Procedures

Data were collected between January and December 2009 as part of a 12-site, randomized, controlled trial, *CTN 0032: HIV Rapid Testing and Counseling in Drug Abuse Treatment Programs in the U.S.* (hereafter, the “parent trial”), conducted to assess the relative effectiveness of three HIV testing strategies on increasing receipt of HIV test results and reducing sexual risk behaviors. The parent trial methods have been published elsewhere [24] and are concisely described here. The trial was conducted among clients seeking drug or alcohol use services at 12 community-based substance use treatment programs across the U.S. in Tucson, Arizona; Plainville and Danbury, Connecticut; Baltimore, Maryland; Cape Girardeau, Missouri; Salisbury, North Carolina; Santa Fe, New Mexico; Portland, Oregon; Pittsburgh, Pennsylvania; Columbia and West Columbia, South Carolina; and Chesterfield, Virginia. Participating community treatment programs represented various treatment modalities and had not offered on-site HIV testing in the previous 6 months before launching the study. Eligible patients were at least 18 years of age, reported being HIV-negative or status unknown, reported no receipt of results from an HIV test initiated within the last 12 months, and were able and willing to provide informed consent.

Participants were randomized to three HIV testing strategies including: (1) on-site, rapid HIV testing in conjunction with HIV risk-reduction counseling, (2) on-site, rapid HIV testing in conjunction with information only (representing the procedures recommended in the CDC’s 2006 guidelines for HIV testing) and (3) a referral for off-site HIV testing (representing treatment as usual). Because these secondary subgroup analyses focus on the efficacy of counseling, only the data from the two on-site rapid HIV testing groups are analyzed. Participants in both groups completed an audio computer-assisted self-interview (ACASI) at baseline and were actively followed at 6 months post-randomization to assess sexual and injection risk behaviors.

Interventions

Group 1, On-site, rapid HIV testing in conjunction with HIV risk-reduction counseling, was based on the single-session RESPECT-2 counseling intervention developed for rapid testing [34] which used a manual-guided, interactive, client-centered, HIV risk-reduction approach to address clients’ barriers to decreasing risk behaviors (e.g., unprotected sex, multiple sex partners, injecting drugs, etc.) as well as validate their previous attempts at risk reduction. The entire pre-test counseling component took approximately 20–25 min to complete and was followed by an offer of rapid HIV testing. Once results were processed (20–40 min), study counselors proceeded with the 15–20-minute post-test counseling component (described elsewhere. [24] *Group 2, On-site, rapid HIV testing in conjunction with information only*, represented the procedures recommended in the CDC’s 2006 guidelines for HIV testing: an offer of HIV testing without required HIV prevention counseling. [11]

Subgroup Analyses

Measures—The subgroup analyses evaluated three dependent variables associated with sexual risk (anal and vaginal sex) for HIV acquisition: (1) number of risky sex acts with any

(primary and non-primary) partners, (2) number of risky sex acts with non-primary partners) and (3) number of sex partners. All were measured at the 6-month follow-up [35, 36]. The first dependent variable corresponds to the primary outcome of the parent trial. The other two dependent variables are among several sexual behavior secondary outcomes that the parent trial examined; they are examined in this paper because they represent higher-level risk factors more focused on HIV risk. The parent trial adapted questions from the EXPLORE study which used a 6-month recall period [35] to ascertain these overall/global sexual behaviors. All independent variables analyzed were based on baseline characteristics collected via the baseline ACASI with three exceptions: age and site were administrative fields populated by study personnel and race/ethnicity was elicited via a face-to-face screening interview. In total, 18 subgroups within four different domains were analyzed; they were selected based on evidence in the literature suggesting that various characteristics are associated with sexual risk behavior and/or HIV prevalence. Subgroups based on demographic characteristics included age [37–39], race/ethnicity [12, 38, 40], biological sex [38], income, [41] and education [41]. Subgroups based on attitudes and perceptions included readiness to use condoms [42], perceived risk for HIV [43, 44], condom use self-efficacy [45, 46], and attitudes toward condoms/safer sex [47]. Subgroups based on risk (type/level) included number of sex acts, number of risky sex acts (anal or vaginal sex without a condom), and drug use severity via the Drug Abuse Screening Test, DAST-10 [48]. Subgroups based on behavioral history included HIV testing history [49, 50], history of injection drug use [15], history of incarceration [51, 52], history of unstable housing [53–56], previous diagnosis of Hepatitis B [41, 57, 58] and relationship status [59, 60]. The 18 variables used to define subgroups were also analyzed as covariates. Other covariates used in multivariable analyses included site, any drug use, any opioid use, any stimulant use, any alcohol use, and depression measured via the 16-item *Quick Inventory of Depressive Symptomatology—Self Report (QIDS-SR-16)* [61].

The subgroups representing attitudes and perceptions were based on established scales. “Readiness to use condoms” was measured by a four-item scale, previously used by Brown-Peterside et al., [42] to assess participants’ readiness to use condoms consistently. The four items facilitate categorization of respondents into one of five stages of change, each of which represents an individual’s readiness to change condom use. The five stages include: precontemplation, contemplation, preparation, action and maintenance. This variable was operationalized as a categorical variable where response 1 = precontemplation and represents participants who are not considering using condoms any time in the next 6 months; 2 = contemplation and represents participants who are considering using condoms sometime in the next 6 months, possibly in the next 30 days; 3 = preparation and represents those who used condoms almost every time that they had sex in the past 30 days and who are planning to start using condoms every time within the next 30 days; and 4 = action or maintenance and represents participants who reported having used condoms every time for the past 30 days. The action and maintenance stages were combined due to small cells.

“Condom use self-efficacy” was measured by the *Condom Use Self-Efficacy Scale, CUSES* [30, 31]. The full scale consists of 28 items; however, the parent trial used only 15 of these items which comprise four distinct sub-scales to measure self-efficacy for (1) the *mechanics* of putting a condom on oneself or the partner, (2) use of a condom even with fear of a

partner's *disapproval*, (3) ability to be *assertive* about condom use with a partner, and (4) ability to use condoms while *intoxicated*. All items were assessed on a five-point ordinal scale in which 1 = strongly disagree, 2 = disagree, 3 = undecided, 4 = agree and 5 = strongly agree. Reliability for these four subscales was good with Cronbach's α ranging from 0.71 for the mechanics subscale, 0.80 for the assertive subscale and 0.86 for both the disapproval and intoxicants subscale. We used the four subscales in their continuous score form as covariates. As subgroups, we dichotomized the variables such that zero was associated with scores on the items of the subscale consistent with answering all items undecided, disagree or strongly disagree and one is consistent with answering on average in the agree or strongly agree range to create subgroups representing low versus high self-efficacy.

"Attitudes toward condoms/safer sex" was measured by the sum of the 13-item *Attitudes Toward Condom Use* subscale from the *Sexual Risks Scale*. [47] All items were assessed on a five-point ordinal scale in which 1 = strongly disagree, 2 = disagree, 3 = undecided, 4 = agree and 5 = strongly agree. Where appropriate, items were reverse scored so that a higher score represents more positive attitudes toward condom use and safer sex. We used the continuous subscale score as a covariate. Reliability for the subscale is quite good with Cronbach's $\alpha = .92$. As a subgroup, we dichotomized using the same procedure as for condom use self-efficacy to create a subgroup representing negative/undecided versus positive attitudes toward condom use and safer sex.

Analysis—Assessment of non-equivalence of the two groups at baseline and 6-month follow-up was performed as part of the parent trial. Analyses demonstrated no evidence of self-selection bias and no evidence of differential attrition. All analyses in the current study were accomplished using Stata version 9.0. Descriptive statistics including, frequency, mean, median, range and 25 and 75th percentiles, were examined by the two treatment groups included in the current study (Table 1).

First, we calculated univariate descriptive statistics including, frequency, mean, median, range and 25 and 75th percentiles, for each of the three outcome variables within each of the subgroups. Second, we evaluated the presence of subgroups on each of the three dependent variables in three main steps. In the first step, we conducted tests of interaction between the treatment variable and each of the 18 independent (subgroup) variable of interest. This was done without covariates to ascertain if there was a simple interaction in the data. We conducted multiple [18] interaction tests.

To ensure that the overall chances of a false-positive result were no more than 0.05, we required each test to meet the stricter criterion of $(1-0.95)/K$ where K represents the number of independent interaction tests undertaken. Therefore, a conservative threshold for determining statistical significance of each interaction test was $(1-0.95)/18 = .0028$. For each dependent measure, we evaluated the relationship between risk-reduction counseling with rapid testing on the dependent measure among different subgroups by first conducting formal tests of interaction between the treatment variable and each independent (subgroup) variable of interest. We did this by introducing a treatment by subgroup interaction term into a model containing only treatment and the subgroup variable of interest. The interaction test tells us that the response to treatment was different in each of the subgroups, but it does not

tell us whether or not the treatment was significantly different than control in any of the subgroups defined by the interaction. Therefore, when an interaction was significant at $p < .0028$, our second step was to perform stratified, univariate tests of the main effect of counseling on the outcome within each of these subgroups, again without covariates to see if there was a simple impact of the intervention within the subgroups. If stratified tests showed a statistically significant ($p < .0028$) main effect of counseling then our third step was to conduct multivariable forward regression to test whether or not this association persisted while controlling for a standard set of baseline variables (gender, age, race/ethnicity, education, total number of sex acts reported in the previous 6 months at baseline and site) as well as other baseline covariates of interest (refer to Measures section for variables) that were selected based on a review of the literature and univariate association ($p < .25$) with the outcome variable. This final step was done to ensure that the treatment effect within the subgroup remained significant when controlling for potential confounders. The standard set of control variables was forced in at the first step of each forward regression and retained in the models regardless of significance. Pairwise correlations of all independent variables were calculated to assess for collinearity prior to entering them into multivariable models. These covariates were not retained in the final multivariable regression models if they were not significant ($p < .05$) and they were not combined in any models if their pairwise correlations were above 0.32. The estimated incidence rate ratio (IRR) for participants who were randomized to the counseling study group compared to the information only study group are presented.

Because the continuous outcome variables, number of risky sex acts with *any* partner, number of risky sex acts with a non-primary partner, and number of sex partners were not normally distributed, a count regression approach was undertaken. All three of these outcomes showed overdispersion (sample variances far exceeded the mean) and therefore a negative binomial distribution was used in each analysis. In addition, the two count variables having to do with risky sex acts showed an excessive number of zeros. Therefore, a zero-inflated negative binomial (ZINB) model, a mixed-effects model that combines two distributions (logistic regression and negative binomial regression) was used. We confirmed that these model assumptions were appropriate using the countfit function in Stata. Again, statistical significance was determined by the p value ($p < .0028$). Model fit was assessed using McFadden's pseudo R^2 . Finally, because the sex partner data appeared to have extreme outliers (whether legitimate cases or due to data entry error), we removed these to prevent increased error variance and reduced power of statistical tests performed. Cases that were more than eight standard deviations from the mean were removed, amounting to three outliers removed from the total partners outcome and two outliers removed from the total partners reported at baseline.

Results

Baseline Characteristics

Screening procedures and detailed reasons for ineligibility are published elsewhere [25]; the 6-month retention rate was 93.7 % and the distribution of lost-to-follow-up and missing data did not differ by group [25]. Because these secondary subgroup analyses focus on the

efficacy of counseling in conjunction with rapid HIV testing, they include only the 849 participants who were randomized to either of the two on-site HIV testing groups. Table 1 contains demographic characteristics and other baseline characteristics of the sample both overall and by the two intervention groups; Table 2 contains these characteristics by intervention group as we provide the overall characteristics in the text. Of these, 418 (61.3 %) were male and 431 (38.6 %) were female. Participants were primarily middle-aged (median age, 40) and of White Non-Hispanic race/ethnicity (59.7 % White Non-Hispanic, 21.9 % Black Non-Hispanic, 11.3 % Hispanic and 7.1 % Other Non-Hispanic). Over one-third (38.2 %) reported having more than a high school education, 76.9 % reported being unemployed during the 6 months prior to enrolling in the study, and 39.3 % had scores on the QIDS-SR [61] consistent with moderate or greater depression in the previous 6 months. Nearly half (48.4 %) of the sample reported having injected drugs in their lifetime and 20.9 % had injected in the 6 months prior to enrolling in the study. Additionally, 73.0 % of participants had DAST-10 scores indicative of having severe substance abuse or dependence (score >6). A total of 77.3 % reported having ever been in jail and 25.2 % reported being incarcerated in the previous 6 months.

The majority of the sample was single (75.3 % single, divorced or widowed; 16.0 % married and 8.7 % unmarried and living with their partner). Nearly one-third (32.0 %) reported having engaged in no vaginal or anal sex within the 6 months prior to enrolling in the study and 39.9 % reported that they had not engaged in any risky sex during this period. The median number of sexual partners was one; median number of sex acts was nine and the median number of unprotected sex acts was five. One-third (34.3 %) of the sample agreed or strongly agreed that they were at risk of contracting HIV and 66.3 % reported positive attitudes toward safer sex. Despite the sample being drug users (a risk group long targeted with HIV prevention and testing efforts), self-reporting recent drug use (in previous 6 months) and being severe substance abusers or dependents, 32.5 % reported having never been tested for HIV in their lifetime.

Post-Randomization Characteristics

During the 6-month period between baseline and follow-up, a sizeable proportion of the sample reported low to no sexual risk. The number of unprotected sex acts with any partner ranged from 0 to 500 acts; the median was 0. Additionally, the median individual reported engaging in 0 unprotected sex acts with *non-primary* partners (range 0–150) during this period and the reported number of sex partners ranged from 0 to 100 partners. The median number of partners during this period was 1. Participants reporting the greatest sex risk were those who reported the following at baseline: (1) being married or unmarried and living together and (2) not having used condoms consistently in the 30 days prior to study enrollment with no intention to use condoms in the 6 months following enrollment (Pre-contemplation stage of condom use readiness).

Association Between Risk-Reduction Counseling and Sexual Risk Behaviors at 6 months Follow-up

There were no statistically significant ($p < .0028$) interactions between the treatment variable and any of the independent (subgroup) variables evaluated for the number of risky sex acts

with any sex partner. Therefore, no further analyses were undertaken with this dependent variable.

We evaluated the number of risky sex acts with non-primary sex partners dependent variable in the same fashion and found no statistically significant interactions at the $p < .0028$ level. Therefore, none were deemed statistically relevant for further exploratory subgroup (stratified) analyses.

We evaluated the relationship between risk-reduction counseling with rapid testing and the number of sex partners among different subgroups in the same fashion via a negative binomial regression model (NBRM) containing only treatment and the subgroup variable of interest. Interactions with four independent variables were statistically significant at $p < .0028$ and, therefore, were deemed statistically relevant for further exploratory analyses. The statistical significance of the stratified univariate tests are shown in Table 3. Results of stratified univariate NBRM reveal that there was a statistically significant ($p < .0028$) main effect of counseling in four relevant subgroups (Table 3). The results of the multivariable modeling for these four statistically relevant subgroups are presented in Tables 4, 5, 6 and 7.

Overall, results of the multivariable analyses showed that counseling (as compared to information only) was associated ($p < .05$) with fewer sex partners in the six-month period between enrollment and follow-up among the following subgroups: participants reporting (1) no risky sex at baseline (IRR = 0.71, 95 % CI [0.54, 0.94], $\chi^2(1) = 5.86$, $p = .02$) (Table 4), (2) low self-efficacy for condom use even with fear of a partner's disapproval (IRR = 0.61, 95 % CI [0.38, 0.97], $\chi^2(1) = 4.33$, $p = .04$) (Table 5), and (3) participants who were assessed as being in the Action/Maintenance stage of condom readiness (IRR = 0.46, 95 % CI [0.27, 0.78], $\chi^2(1) = 8.24$, $p = .004$) (Table 6). (4) The direction of the effect (IRR = 1.48, 95 % CI [1.09, 1.99], $\chi^2(1) = 6.35$, $p = .01$) (Table 7) was reversed, with participants in the counseling group having more total sex partners in the 6-month period between enrollment and follow-up, among participants who were assessed as being in the contemplation stage of condom readiness. Additionally, within all four models, older age was related to having fewer partners; within three models, having engaged in any vaginal or anal sex in the 6 months prior to enrollment was related to having more partners; in two models, having more total partners within 6 months prior to study enrollment was related to having more partners at follow-up; and in two models, Hispanic race/ethnicity was related to having fewer sexual partners in the 6-month period between enrollment and follow-up.

Discussion

The goal of the current analysis was to evaluate the efficacy of HIV risk-reduction counseling in conjunction with HIV rapid testing on the sexual risk behavior of different subgroups of substance use treatment clients. This goal was accomplished by conducting a series of post hoc, exploratory subgroup analyses. Overall, findings of this study lend support for routine HIV testing without requiring HIV risk-reduction counseling at the time of testing. Specifically, findings suggest that brief HIV risk-reduction counseling in conjunction with rapid HIV testing is not efficacious in reducing number of risky sex acts among subgroups of substance use treatment clients. Results also suggest that most

subgroups did not experience an effect of counseling (versus information only) on the total number of sex *partners*. There was, however, a significant effect ($p < .0028$) of counseling on total number of sex partners among some subgroups.

Subgroups in which there was a significant effect of counseling on total number of sex partners encompassed participants who reported no or low risky sex behaviors prior to enrollment and those who had low self-efficacy for condom use. It is not surprising that counseling was related to *fewer* sex partners among participants reporting no risky sex in the 6 months prior to study enrollment given that the counseling intervention could have reinforced existing no/low-risk behaviors such as abstinence or monogamy. Also, having sex with *fewer* partners may have resonated as an additional protective strategy among subgroups that were already practicing safer sex behaviors at baseline, including those who were assessed as being in the action/maintenance stage of condom readiness. Counseling was related to *fewer* total partners among the subgroup of participants whose baseline responses indicated that they had low self-efficacy for condom use even with fear of a partner's disapproval (Table 5). One explanation for this relationship may be that participants in this group had low self-efficacy for condom use due to their dislike of condoms and perhaps they had no/little intention to use them. Therefore, the study counselor may have chosen to focus on partner reduction rather than condom use as a more attainable HIV prevention strategy.

Among individuals who reported not using condoms consistently within 30 days prior to study enrollment, but considering using them within the next 6 months (contemplation stage of condom readiness), those who received counseling reported nearly 1.5 fold the number of sex partners (compared to those in the information only group) at follow-up. Given that 32.0 % of the sample reported having engaged in no vaginal or anal sex in the 6 months prior to enrolling in the study, it is plausible that these no-risk individuals are driving this effect. More specifically, individuals in this stage of readiness to use condoms may not have been in a sexual relationship at baseline, but may have been contemplating beginning a sexual relationship in the near future. Therefore, the focus of their counseling may have been on consistent condom use with a future sex partner rather than on reduction of sex partners. Alternatively, it is possible that discussion of sexual behaviors in the counseling group led to increased sex (potentially safer sex) with an additional partner(s). Additionally, as with any statistical analysis, the increase in number of sex partners for participants in this contemplation stage of condom readiness group may also be the result of (5 %) chance.

Overall, the results of the analyses on total number of partners suggest that brief, client-centered HIV risk-reduction counseling may be efficacious in reducing total number of sex partners among low-risk participants (e.g., those with no baseline risky sex and those already consistently using condoms) in substance use treatment. However, focusing efforts on low-risk individuals may not be productive. These findings are somewhat contrasting to the results of subgroup analyses from the original RESPECT trial which found that individuals at highest risk reaped the most benefit from RESPECT Brief Risk-Reduction Counseling [38]. However, our findings should be viewed with caution given the number of post hoc subgroup analyses that were performed and the potential increase in Type I errors (false positives) due to multiple testing despite correcting for this multiplicity.

Limitations

There are several limitations that readers should consider when interpreting this research, many of which have to do with design and measurement. The outcome is based on self-report which may be subject to recall bias and/or social desirability bias. To minimize social desirability bias, we collected sexual and drug use behavior data via ACASI which may reduce social desirability and, therefore, capture more accurate reports of outcome and other data of a sensitive nature (e.g., substance use data) [62]. However, we did not collect data on self-reported honesty or social desirability to help evaluate the validity of the self-reported condom use measures [63]. Additionally, we lack measures of some potentially important covariates of sexual risk behavior, including but not limited to measures of correct condom usage, self-efficacy for implementing the risk-reduction plan, intentions to conceive a child, who initiated condom use, sex trading behaviors (e.g., sex for money, drugs, food or shelter), and duration of substance use treatment at baseline or follow-up to assess how treatment may moderate or mediate the relationship between the intervention and sexual risk behavior.

Other design and analytic issues limit our findings. The study was powered to detect differences between interventions and not differences among specific subgroups. Therefore, we may have insufficient sample sizes in subgroups to ensure that our findings are statistically significant; findings should be interpreted with caution. Another factor was the 6-month recall period for sexual risk behaviors, which has lower reliability than shorter periods of recall. Additionally, there was no inclusion criterion concerning recent anal/vaginal sex; the baseline levels of anal/vaginal sex and sex risk in this sample were low. The median number of sexual partners reported in the 6 months prior to enrollment was one. This lack of baseline sexual intercourse and sexual risk may affect the ability of the analyses to find lower sexual risk behavior associated with counseling. Finally, because we studied substance use treatment programs, we do not know if the findings are generalizable to other health care settings. However, a recent study conducted in sexually transmitted diseases clinics by the same lead investigators found similar results, no benefit of brief, client-centered HIV risk-reduction counseling delivered in conjunction with rapid HIV testing on self-reported risk behaviors or STI incidence [64].

Because client-centered counseling is not a fixed intervention (i.e., it provides basically the same dosage of intervention, but its content varies according to the client's disclosed risk behaviors and desired risk-reduction goals), it's purported strength (being tailored to a given client's needs) may also be its weakness, at least among substance users. For example, it is reasonable to assume that due to the client-centered nature of the counseling evaluated in this study, the content of the counseling may vary as a function of the client/participant. Among substance users, in particular, it is possible that counselors deemphasized sexual routes of transmission in favor of substance using routes that may have been more salient for the client [65].

Another consideration with respect to client-centered counseling being a flexible intervention is that the results of the parent trial and subgroup analyses may have been different if another outcome(s) had been used to evaluate the counseling intervention. Other appropriate outcomes (or combinations of outcomes) that could have been evaluated and which may be considered in future analyses are: percentage of time that condoms were used,

change in sex risk behaviors (number of sex acts, unprotected sex acts or partners) from baseline to follow-up, and total number of partners with whom participants have engaged in sex risk behaviors.

The fact that CTN 0032 participants were not actively seeking HIV testing and counseling at the time of their study enrollment may also have affected their receptivity to the counseling. Weinhardt et al. [66] found that participants who sought HIV testing and counseling on their own reduced their frequency of risky sexual behavior more than those participants who were offered HIV testing and counseling as part of research. Further, participants who sought HIV testing and counseling may have done so as part of a larger risk-reduction plan/strategy [66]. Weinhardt et al. [66] concluded that research with participants who do not actively seek HIV testing may not accurately reflect the effects of HIV testing and counseling as it is truly implemented in the real world.

Implications and Future Directions

According to the 1993 Technical Guidance on HIV Testing [67], changing high-risk behavior is not an “all-or-nothing” process. The CDC cautioned that even after receiving HIV counseling and testing services, HIV-negative individuals may continue to engage in risky behaviors that may lead to acquisition of HIV. The guidance, therefore, encouraged counselors to view all clinical encounters with clients as potential opportunities to provide and reinforce HIV-prevention messages. In particular, HIV-negative clients who are at increased risk for HIV infection may require additional counseling to develop the *skills* needed to practice safer behaviors [67]. Therefore, it is possible that a single dose of brief HIV risk-reduction counseling is not enough to see reduced risky sexual behavior 6 months later. It is conceivable that booster counseling delivered at subsequent encounters may be effective [8, 38]. Future studies should examine the effect of subsequent booster counseling with and without HIV rapid testing on the effect of risky sexual behavior among substance use treatment clients.

Given that (1) drug users are at greater risk for contracting HIV than the general population, (2) the outcome results of this study are, overall, contrary to those in the RESPECT study, and (3) there are several limitations of the CTN 0032 study, a process study may be warranted to facilitate exploration of exactly how and why counseling did not result in reduced risk behaviors among substance using clients. A process study could be undertaken to empirically measure the counseling “dose” delivered in this study. Additionally, qualitative analyses of the risk-reduction plans that were created as part of the counseling intervention may be performed to gain a better understanding of the specific behavioral goals that were established for the individual participants. Analyses of self-efficacy and/or attitudes toward condom use as proximal outcomes may also be performed.

Finally, subgroup analyses of clinical trial data can be controversial [68–77] mainly due to the high likelihood of Type I error and lack of replicability [70] when an extensive list of interactions with treatment are tested. Whereas we have corrected for the multiple testing, thus holding our Type I error with respect to interaction testing equal to 0.05, the patterns of subgroup results we have found are modest. We have not examined higher-order interactions, where multiple characteristics might jointly define a subgroup for whom

counseling does or does not work well. Machine learning techniques such as random forests [33, 78, 79], may be methods which would allow the inclusion of complex interactions and yet identify replicable sets of predictive factors. Current research efforts are examining use of these methods to find subgroups with differential treatment responses [33, 79].

Conclusions

In conclusion, results of the analyses on total number of partners suggest that brief, client-centered HIV risk-reduction counseling may be efficacious in reducing total number of sex partners among low-risk participants (e.g., those with no baseline risky sex and those already consistently using condoms) in substance use treatment. However, because the majority of subgroups investigated did not report fewer sexual risk behaviors (acts or partners), the overall findings of this study lend support to the CDC's 2006 recommendation to provide routine HIV testing without requiring HIV risk-reduction counseling at the time of testing. Findings should be viewed with caution given the number of post hoc subgroup analyses that were performed.

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Table 1

Sample characteristics overall and by study group: frequencies and percentages

Characteristic	Information only (%)	Counseling (%)	Total
Race/ethnicity			
Hispanic	11.2	11.4	11.3
Black	21.8	22.0	21.9
White	59.8	59.6	59.7
Other	7.2	7.0	7.1
n	418	431	849
Female	38.3	39.0	38.6
n	418	431	849
Income			
\$10,000	66.6	64.2	65.4
\$10,001–\$30,000	25.0	25.5	25.2
>\$30,000	8.4	10.40	9.4
n	416	424	840
Education			
<High school/GED	25.8	27.8	26.9
High school/GED	36.6	33.4	35.0
>High school/GED	37.6	38.8	38.2
n	418	431	849
Ever tested for HIV	69.4	68.9	69.1
n	418	431	849
Years since HIV tested			
Never	32.1	32.9	32.5
>0 to 1 year ago	4.0	3.7	3.9
>1 to 2 years ago	18.1	12.3	15.1
>2 to 5 years ago	20.6	21.9	21.2
>5 years ago	25.3	29.2	27.3
n	399	407	806
Any lifetime intravenous drug use	49.3	47.6	48.4
n	418	431	849
Any intravenous drug use in last 6 months	20.3	21.4	20.9
n	418	431	849
Any opioid use in last 6 months	39.5	38.8	39.1
n	418	431	849
Any stimulant use in last 6 months	43.3	43.9	43.6
n	418	431	849
Any use of alcohol in last 6 months	74.9	70.8	72.8
n	418	431	849
Drug use severity (DAST score > 6)	68.9	77.0	73.0
n	418	431	849

Characteristic	Information only (%)	Counseling (%)	Total
Readiness to use condoms			
Precontemplation	47.0	45.9	46.4
Contemplation	38.9	41.0	40.0
Preparation	6.5	3.9	5.2
Action or maintenance	7.5	9.3	8.4
n	398	410	808
Lifetime history of incarceration	76.3	78.2	77.3
n	418	431	849
History of incarceration in past 6 months	24.2	26.2	25.2
n	417	431	848
History of unstable housing	1.4	1.6	1.5
n	418	431	849
Previous diagnosis of Hepatitis B	7.7	6.1	6.9
n	417	427	844
BL Employed in past 6 months	24.9	21.4	23.1
n	418	430	848
Relationship status			
Married	14.6	17.4	16.0
Unmarried and living with partner	8.6	8.8	8.7
Single, divorced, or widowed	76.8	73.8	75.3
n	418	431	849
Depression score			
Not depressed	32.1	31.8	31.9
Mild	27.8	29.7	28.7
Moderate	23.7	23.0	23.3
Severe	12.7	11.4	12.0
Very severe	3.8	4.2	4.0
n	418	431	849

Table 2

Sample characteristics by study group: mean, median, 25th and 75th percentile

	Information only					Counseling				
	N	Mean	Median	25th pctile	75th pctile	n	Mean	Median	25th pctile	75th pctile
Age (years)	418	39.6	40.0	30.0	48.0	431	39.6	40.0	30.0	48.0
No. times tested for HIV in lifetime	292	2.7	2.0	1.0	3.0	297	2.7	2.0	1.0	3.0
BL no. of sex acts in past 6 months	418	39.2	8.0	0.0	45.0	431	39.6	10.0	0.0	50.0
BL no. of risky sex acts in past 6 months	418	33.1	4.0	0.0	30.0	431	33.5	5.0	0.0	34.0
BL no. of partners in past 6 months	409	2.3	1.0	0.0	2.0	426	2.6	1.0	0.0	2.0
Attitudes toward condoms/safer sex (range 5–65)	418	44.3	46.0	36.0	53.0	430	44.0	45.0	36.0	52.0
Depression Score	418	9.4	8.0	4.0	14.0	430	9.2	8.0	5.0	13.0
Condom use self-efficacy (CUSE) total	418	60.3	63.0	53.0	69.0	430	61.0	63.0	55.0	70.0
CUSE Partner Disapproval Scale	418	20.4	21.0	18.0	25.0	430	20.2	21.0	18.0	24.0
CUSE Mechanics Scale	418	16.5	17.0	15.0	20.0	430	16.9	17.0	15.0	20.0
CUSE Assertive Scale	418	12.5	13.0	11.0	15.0	430	12.9	14.0	12.0	15.0
CUSE Intoxicated Scale	417	11.0	12.0	9.0	14.0	430	11.0	12.0	9.0	14.0

Table 3

Interaction tests and stratified univariate tests of the main effect of counseling on the number of partners in the past 6 months within each subgroup deemed statistically relevant ($p < 0.0028$) for further exploratory analyses

Subgroup	IRR ^a	95 % CI	χ^2	P value
Stages of change for condom use ^b			61.04	< .001
Precontemplation	0.69	(0.54, 0.88)	8.82	.0030
Contemplation	2.46	(1.75, 3.48)	24.42	< .001
Preparation	0.55	(0.23, 1.30)	1.85	.17
Action or maintenance	0.29	(0.16, 0.31)	19.54	< .001
Unprotected BL sex acts			19.27	< .001
None	0.59	(0.42, 0.84)	8.88	.0028
Any	1.19	(0.95, 1.48)	2.37	.12
Condom use self-efficacy (CUSE)–partner disapproval scale			10.43	.001
Low efficacy	0.43	(0.27, 0.71)	11.02	.001
High efficacy	1.23	(1.00, 1.50)	3.92	.05
CUSE–assertiveness scale			8.94	.0028
Low efficacy	0.39	(0.21, 0.73)	8.76	.0030
High efficacy	1.20	(0.98, 1.47)	3.42	.06

^aIRR refers to the estimated incidence rate ratio

^bThe Chi square value and p value are the only statistics reported for the interaction test. The interaction test for stages of change for condom use is 3 degrees of freedom (df). All other interaction tests are 1 df

Table 4Multivariable negative binomial regression model: reported no *Risky* sex at baseline interaction

pseudo R ²				N
0.18				305
No. of partners in past 6 months	IRR ^a	95 % CI	χ^2	P value
Counseling	0.71	(0.54, 0.94)	5.86	.02
BL no. of partners in past 6 months	1.09	(1.05, 1.12)	25.60	< .001
Female	0.86	(0.63, 1.17)	0.98	.32
Race/ethnicity				
White	Ref			
Black	1.11	(0.74, 1.66)	0.26	.61
Hispanic	1.29	(0.81, 2.06)	1.19	.28
Other	1.68	(1.01, 2.81)	3.96	.05
Age (years)	0.97	(0.95, 0.98)	28.09	< .001
Education				
<High school	Ref			
High school/GED	0.91	(0.65, 1.29)	0.28	.60
>High school	1.05	(0.74, 1.50)	0.08	.78
Any BL sex acts	2.14	(1.59, 2.88)	25.40	< .001
Marital status				
Married	Ref			
Unmarried and living with partner	0.44	(0.21, 0.92)	4.80	.03
Single, divorced, or widowed	0.55	(0.37, 0.84)	7.67	.006

^aIRR refers to the estimated incidence rate ratio

Table 5

Multivariable negative binomial regression model: reported low self-efficacy for condom use even with fear of partner's disapproval interaction

pseudo R ²				N
0.13				115
No. of partners in past 6 months	IRR ^a	95 % CI	χ ²	P value
Counseling	0.61	(0.38, 0.97)	4.33	.04
BL no. of partners in past 6 months	1.02	(0.96, 1.09)	0.52	.47
Female	1.51	(0.86, 2.66)	2.07	.15
Race/ethnicity				
White	Ref			
Black	1.23	(0.67, 2.28)	0.45	.50
Hispanic	0.30	(0.09, 0.97)	4.04	.04
Other	0.47	(0.17, 1.29)	2.16	.14
Age (years)	0.96	(0.94, 0.99)	7.51	.006
Education				
<High school	Ref			
High school/GED	0.77	(0.45, 1.34)	0.86	.35
>High school	0.61	(0.31, 1.20)	2.04	.15
Any BL sex acts	2.10	(1.03, 4.30)	4.12	.04

^aIRR refers to the estimated incidence rate ratio

Table 6

Multivariable negative binomial regression model: action/maintenance stage of condom readiness interaction

pseudo R ²				N
0.27				61
No. of partners in past 6 months	IRR ^a	95 % CI	χ^2	P value
Counseling	0.46	(0.27, 0.78)	8.24	.004
BL no. of partners in past 6 months	1.10	(1.05, 1.14)	20.16	< .001
Female	0.99	(0.56, 1.76)	0.002	.97
Race/ethnicity				
White	Ref			
Black	1.24	(0.65, 2.38)	0.44	.51
Hispanic	0.33	(0.13, 0.84)	5.38	.02
Other	0.73	(0.16, 3.41)	0.16	.69
Age (years)	0.96	(0.94, 0.99)	9.67	.002
Education				
<High school	Ref			
High school/GED	1.49	(0.77, 2.89)	1.42	.24
>High school	1.10	(0.61, 1.98)	0.09	.76
Condom use self-efficacy mechanics scale	0.87	(0.80, 0.95)	10.18	.001

^aIRR refers to the estimated incidence rate ratio

Table 7

Multivariable negative binomial regression model: contemplation stage of condom readiness interaction

pseudo R ²				N
0.18				289
No. of partners in past 6 months	IRR ^a	95 % CI	χ^2	P value
Counseling	1.48	(1.09, 1.99)	6.35	.01
BL no. of partners in past 6 months	1.11	(1.07, 1.15)	31.81	< .001
Female	0.91	(0.66, 1.27)	0.29	.59
Race/ethnicity				
White	Ref			
Black	1.17	(0.81, 1.70)	0.71	.40
Hispanic	1.30	(0.74, 2.28)	0.81	.37
Other	1.20	(0.71, 2.05)	0.46	.50
Age (years)	0.97	(0.96, 0.98)	19.54	< .001
Education				
<High school	Ref			
High school/GED	0.77	(0.53, 1.12)	1.88	.17
>High school	1.13	(0.77, 1.66)	0.38	.53
Condom use self-efficacy mechanics scale	1.08	(1.02, 1.13)	8.18	.004

^aIRR refers to the estimated incidence rate ratio