Published in final edited form as:

AIDS Behav. 2012 July ; 16(5): 1192–1202. doi:10.1007/s10461-011-0104-y.

Cognitive Behavioral HIV Risk Reduction In Those Receiving Psychiatric Treatment: A Clinical Trial

Robert M. Malow*,
Florida International University

Robert McMahon*,
University of Miami

Jessy Dévieux,
Florida International University

Rhonda Rosenberg,
Florida International University

Anne Frankel,
Florida International University

Vaughn Bryant,
Florida International University

Brenda Lerner, and
Florida International University

Maria Jose Miguez
Florida International University

HIV seroprevalence estimates range from 5.2–22.9% in the severely mentally ill (SMI) depending on population factors including gender, substance abuse, and region of residence, namely metropolitan or non-metropolitan (1). Regardless of the actual HIV rate among SMI, researchers agree that rates are higher than in the general population (2). Further, HIV prevention researchers routinely report high rates of risky sexual behavior such as multiple sexual partners, trading sex for drugs, and unprotected sex (2–4), not to mention high rates of injection drug use in SMI populations (5).

SMI studies have most frequently used small group interventions with some meaningful short term results (4, 6). Thus far, it has been found that reductions in risk behavior tend to fade with time and are less than impressive in those with more severe psychiatric impairment. Successful interventions are most often defined as those that not only increase HIV/AIDS knowledge and produce more positive attitudes towards safe sex, but ultimately result in less sexual risk behavior. An early review determined that the most efficacious interventions had many sessions, which can be a challenge for a transitive SMI population (7). The same review found that successful interventions integrated techniques to mediate multiple risk determinants, often by utilizing role play, modeling, and identification of personal risk triggers. In their 2008 review, Senn and Carey found that interventions which included motivational or attitudinal components, as well as skills components, saw the most

Correspondence to: Dr. Robert Malow, Florida International University, Biscayne Bay Campus, 3000 NE 151 St – AC1 #260, Miami, Florida 33191, Phone: 305-919-4205, Fax: 305-919-4220, rmalow@bellsouth.net.

*Note. Drs. Malow and McMahon contributed equally to this paper. Their names are listed in alphabetical order. The authors would also like to thank Terri Jennings for her contributions to the paper.

improvements in knowledge, attitudes, and behavior (2). Repeating information and material and using language tailored to the population also had positive effects. However, Senn and Carey also found that too few studies assessed the impact of an intervention on sexual behavior change, focusing instead on changes in attitudes or motivations. Other limitations to previous interventions include small sample sizes, short follow-up periods, and low rates of sexual risk behavior at baseline.

Carey et al. conducted a strong test of treatment efficacy, comparing a theoretically anchored HIV-transmission risk reduction intervention tailored specifically for SMI with an alternative substance use reduction intervention that, although not targeted directly at HIV-risk behavior, could be expected to reduce risk behavior indirectly (4). Their intervention was guided by the Information Motivation Behavior (IMB) model (8), which presumes reduced risk (e.g., condom use) will occur if individuals are well-informed about HIV transmission and prevention, motivated to modify risk, and capable of utilizing the necessary interpersonal and self-regulation skills needed to avoid risk behavior. Carey et al. supports specific efficacy for an intervention tailored for SMI patients and the HIV risk reduction efficacy of a general substance use reduction intervention that did not target sexual behavior specifically – but did address presumed risk reduction behavior mediators (motivation, skills) (4). Those with SMI receiving the HIV treatment risk reduction intervention reported favorable changes in casual sex partners, unprotected sex, new sexually transmitted infections, safer sex communication, HIV knowledge, positive condom attitudes, condom use intentions, and behavioral skills. SMI patients receiving the substance abuse reduction intervention reported fewer total and casual sex partners compared with control patients. Consistent with Otto-Salaj, et al. (6), Carey and associates found that women showed greater risk reduction than men. However, both Carey et al. and Otto Salaj et al. found that men demonstrated greater improvement in important HIV risk antecedents (4, 6).

During our development phase, we performed an extensive review of intervention literature, and found “HIV Prevention for People with Mental Illness, A Training Manual for Mental Health Professionals- 4th Edition” (9) to be a close match to our conceptual model. The manual had been through numerous revisions, used extensively with SMI populations, and had not yet been tested in a randomized trial approach. After pilot testing, feedback from the interventionists, discussion with treatment providers and experts in the fields conducting HIV prevention research with psychiatric disturbed populations (e.g., Otto-Salaj, Cournos, McKinnon, Klinkenberg, St. Lawrence, R. DiClemente) and rapid developments in the HIV/AIDS area, we revised the manual in several ways. First, given the recent and dramatic improvements in treating HIV (i.e., combination antiretroviral regimes) that might significantly affect the decision to be tested, we added content to encourage routine HIV testing to promote early identification and treatment of HIV. Second, given the literature showing that many recovering alcohol and other drug (AOD) abusing SMI patients often relapse to HIV risk, AOD use, and occurrence of psychiatric symptoms (e.g., mood disturbance, impulsivity, psychotic thinking), our revised intervention emphasizes long-term relapse prevention maintenance strategies for reducing AOD use and psychiatric symptoms (e.g., enhancing adherence to psychotropic medication; (10)). Third, we adapted Motivational Enhancement Therapy procedures that have been effective in enhancing AOD abuse recovery (11). This is likely to be important with the SMI who have been shown to often lack motivation for enacting health behavior change and have benefited from including motivational enhancing strategies in their treatment (12–14). In our pilot study, we found that, post-intervention, many SMI could demonstrate adequate skills and knowledge associated with reducing risk, but lacked the motivation to do so. Fourth, we chose to limit our intervention to 6 sessions. In the literature, many interventions are of this length or

shorter given increasingly fewer resources available for HIV prevention efforts, and experts in the area have been encouraging shorter (less than 6 sessions) interventions.

For this study, we compared an enhanced cognitive-behavioral skill building intervention (E-CB) intervention with a health promotion comparison (HPC). Like Carey et al., we based the intervention on the tenets of the IMB model. The IMB model posits that HIV prevention information, HIV prevention motivation, and HIV prevention behavioral skills are the important determinants of HIV preventive behavior. Knowledge that is directly relevant to HIV prevention and that can be reasonably utilized in the individual's social context is considered prerequisite for HIV preventive behavior (15) and includes specific facts relating to HIV transmission (i.e., Anal sex is risky because it transmits HIV) and HIV prevention (i.e., Condoms make intercourse completely safe.) Motivation to engage in HIV preventive acts determines whether even well-informed individuals will be inclined to act on what they know about prevention (15) and includes condom attitudes, behavioral intentions, perceptions regarding social support for performing such acts (i.e., Partner and Peer Attitudes Regarding Safer Sex), and perceptions of personal vulnerability to HIV infection (i.e., Perceived Susceptibility). Finally, behavioral skills and perceived personal efficacy include objective ability (i.e., Condom Use Skills) and perceived self-efficacy in maintaining a pattern of preventive behavior.

Consistent with the IMB model, the E-CB condition focused on HIV- risk education, motivational enhancement and goal setting, developing condom use skills and risk reduction practices through problem-solving, assertiveness, and communication training. It included specific training on how substance abuse and psychiatric symptoms may contribute to HIV risk and incorporated strategies to manage these risks. The HPC condition included a single session of HIV risk reduction education, but primarily emphasized various other health and wellness promoting activities aimed at improving health, including cardiovascular, dental and nutritional health, physical activity, eliminating tobacco use, and managing stressful emotions – all areas that may challenge SMI patients. Despite the differences in session material, the E-CB and HPC conditions matched in duration and format, such that they each contained 6 90-minute sessions over 6 weeks. Both interventions were adapted to the special needs and capacities of those with SMI. These adaptations included identifying high risk factors for relapse (e.g., emotional factors); identifying environmental cues for relapse (e.g., people, place, time of day); and teaching cognitive-behavioral strategies (e.g., self-monitoring) for decreasing AOD use and other psychiatric symptoms. During these sessions, we repeatedly emphasize how the emergence of psychiatric symptoms (hallucinations, delusions, manic patterns of behavior, and depression) is likely to increase the probability of high-risk sexual behaviors.

Relative to the HPC group, the E-CB group was hypothesized to show significant changes in attitudes and beliefs relevant to HIV risk reduction (i.e., perceived susceptibility, HIV-anxiety, sexual self efficacy, intentions to practice safer sex, attitudes regarding condom use). Adoption of safer sexual practices in the HPC group was expected to be associated with intervention targeted improvements in general health and wellness, but superior improvements in sexual practices were anticipated in the E-CB group. E-CB and HPC groups were hypothesized to demonstrate comparable reductions in knowledge regarding HIV-transmission risk as both interventions targeted this outcome. We also anticipated meaningful improvements in safer practices (fewer sexual partners, fewer unprotected vaginal sex acts, smaller proportions of unprotected vaginal sex acts) in both E-CB and HPC groups. Finally, because there is evidence that the antecedents, correlates, risk behavior outcomes, and HIV prevention intervention effects differ by gender (4, 6) we evaluated gender differences in intervention response. Previous studies of gender outcomes have

shown mixed outcomes among SMI populations; for example, women are more likely to have unprotected sex and trade sex for money, but men are more likely to pay for sex (5).

Methods

Participants

Participants were recruited from 16 inner-city treatment programs for the mentally ill in Miami-Dade Florida. Trained undergraduate and master's degree level interviewers approached potential participants to explain the study and obtain informed consent. Interviewers evaluated participants' understanding of study requirements, taking care in providing clarification and responding to questions. Participants included 102 males and 120 females attending day and residential mental health treatment. Potential participants were excluded from the study if they did not meet the following criteria: (a) residence in Miami-Dade County, FL; (b) access to transportation to study sites; (c) English as a primary language; (d) drug or alcohol use in the past 6 months; and (e) characterized as SMI. Several participants were excluded due to evidence of severe cognitive dysfunction, prohibiting participation in study sessions.

Assessment Procedures

The trial was started in 1998, when initial pilot testing and intervention development commenced, and data collection finished in 2002. Participants were grouped by study site and randomly assigned to the E-CB or HPC condition. All assessment procedures were conducted by experienced interviewers, trained to create an assessment process sensitive to gender and cultural issues as well as to adopt a non-judgmental attitude to establish rapport and build trust. To prevent interviewer drift and other contaminating factors, assessors received ongoing supervision from a licensed clinical psychologist throughout the study. Assessors were also blinded to the assigned condition of the participant they were interviewing for post-intervention and follow-up assessments in an effort to prevent bias. Following informed consent, assessment measures were verbally administered to facilitate full completion and compensate for literacy difficulties. Interviewers were careful to ensure that respondents understood the meaning of each question. In the event that a respondent showed any confusion, an assessor would repeat or elaborate on questions as required.

A manual and a procedural checklist were used to ensure standard administration of assessment measures. Interviews were conducted in a private room to guarantee confidentiality and enhance compliance. Interviewers used key events and calendar time lines to facilitate accurate reporting of the participants' behavior over the recall period. Assessments were administered at 6 different time points: prior to the intervention, after the intervention (anywhere from 6 weeks to 2 months after the pre-assessment), and at 2-month intervals thereafter: 4 months, 6 months, 8 months, 10 months, and 12 months.

Measures

Psychiatric diagnoses were gathered from participants' clinical records at study sites. Researchers used the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) to determine current Axis I and Axis II disorders (16).

The Addiction Severity Index (ASI) interview was chosen to gather sociodemographic information (gender, age, self-identified ethnic background, and marital status), lifetime alcohol and drug problem history and psychiatric symptoms. The ASI has shown high concurrent and inter-rater reliability (.74 to .93) and validity among a similar SMI samples, including those in drug treatment (17).

HIV Risk Moderator Variables—HIV risk variables included *factual knowledge* regarding HIV transmission (18), *perceived susceptibility* (perceived risk for contracting HIV) (19), *AIDS-related anxiety* (anxiety about becoming infected with HIV) (19), *sexual self-efficacy* (confidence in adopting and maintaining HIV preventative behavior) (19), *personal attitudes towards condoms* (19), *condom use skills* (participant's ability to properly enact nine steps to correctly place a condom on a penile model) (20), *sexual attitudes* (participant beliefs about peer and partner support for enactment of safer practices and the perceived importance of such support) (21), and *behavioral intentions*, which assessed participants' intention to take future actions to reduce HIV risk (e.g., "I will use a condom the next time I have sex") (6). *Factual knowledge* about HIV transmission was assessed using an 18-item true/false questionnaire (18). All of the other scales listed above have 4/5-point Likert formats with response options ranging from "strongly disagree" to "strongly agree" on various statements. These scales have been shown to mediate HIV risk and have demonstrated validity and reliability among similar samples (22–24).

Risk Behavior Assessment (RBA) (25) has shown adequate test-retest reliability for sexual risk behaviors (26) and is similar to other sexual risk behavior measures used for SMI adults (27). Variables derived from the RBA included total number of sexual partners, number of unprotected vaginal sex acts, and proportion of vaginal sex acts unprotected.

Intervention

In the current investigation, elements of several HIV Risk Reduction Programs (18, 21, 28) were integrated into an IMB framework emphasizing HIV-risk information, motivational enhancement, and risk reduction behavioral skills tailored for use in an SMI population. Both E-CB and HPC interventions were composed of six 90-minute sessions, spread over the course of 6 weeks.

E-CB Format—Based on literature review, consultation with experts in the field (e.g., Kalichman, Carey, McKinnon, Otto-Salaj, St. Lawrence), and our pilot experience, we adopted the following format and procedures in conducting the E-CB intervention:

First, we chose a small group approach because it is cost-effective and provided the opportunity for participants to acquire and rehearse risk reduction skills and develop social support and reinforcement. Second, because many recovering AOD dependent SMI patients suffer problems with attention, comprehension, and memory, we employed various procedures to help participants learn and retain presented material including 1) adopting a lively and interactive format, 2) presenting information in a repetitive and concrete manner using multiple modalities (i.e., visual and oral) and strategies (modeling, role-plays, video games) with ample opportunities for practice, feedback, and reinforcement. Third, we included HIV+ participants because: a) it is important to investigate HIV transmission risk reduction among this group b) most SMI treatment programs conduct mixed serostatus groups, c) it would have been hard to maintain serostatus anonymity if we ran separate serostatus groups. Unless a participant revealed his/her serostatus, facilitators and group members were unaware of it. Participants rarely disclosed such information. Fourth, we chose to conduct 6 sessions – one per week to enable participants to practice lessons.

E-CB content—Session 1 & 2 focused on developing group cohesion, HIV education, and personalizing HIV risk. We addressed discomfort regarding sexual behavior and language, emphasized the ease with which sexually transmitted diseases are spread, discussed personal vulnerability to HIV and distributed resources concerning HIV, STDs and pregnancy. Sessions 3 & 4 focused on developing condom use and safe sex negotiation skills through employing problem solving, assertiveness and communication training approaches. Training

was provided in safer sex communication and skill acquisition that included modeling effective negotiation, role play involving condom initiation and partner refusal, and group feedback. Sessions 5 and 6 were specifically focused on identifying high-risk situations and practicing previously learned communication and negotiation skills. The following components were included to help reduce relapses to AOD use: identifying high risk factors for relapse (e.g., emotional triggers); identifying environmental cues for relapse (e.g., people, place, time of day); teaching cognitive-behavioral strategies (e.g., self-monitoring) for decreasing AOD use and increasing response and self-efficacy; overcoming personal barriers to safer sex; and recognizing personal resources.

HPC content—Session 1 presented information about HIV (e.g., transmission and prevention strategies), and about developing and maintaining a healthy lifestyle. Topics included anatomy and physiology of the circulatory system, heart health, nutrition, physical activity, relaxation for stress management and other health risk factors such as cigarette smoking. Session 2 offered information about heart attacks and the structure of the heart including a description of the heart. Session 3 focused on encouraging recognition of the contribution of good food habits in promoting a healthy lifestyle (i.e., carbohydrates, proteins, fats, vitamins, minerals, and water). Session 4 encouraged the recognition that exercise can enhance physical and emotional well-being and promoted understanding of the social, cultural, and psychological factors that influence exercise. Session 5 focused on building awareness of the dangers of smoking (i.e., listing harmful substances found in cigarette smoke), on providing positive nonsmoking images, and on providing support for the decision to be tobacco-free. Finally, Session 6 consisted of identifying the basic sources of stress and what happens to the body when in a state of stress and providing information/training on stress management techniques including relaxation exercises designed to keep stress within reasonable limits.

Data Analytic Plan

We were interested in the impact of two intervention conditions on our primary outcome variable, sex risk behaviors, as well as informational and motivational antecedents of risk behavior, behavioral skills, and self-efficacy. Knowledge regarding HIV infection and prevention, perceived HIV infection susceptibility, anxiety regarding HIV infection, condom attitudes, peer and partner attitudes regarding safer sexual practices, safer sex behavioral intentions, condom use skills, self-efficacy regarding safer sex, number of unprotected vaginal sex acts, proportion of unprotected vaginal sex acts, and number of sexual partners, were analyzed using 2 (treatment condition), x 2 (gender), x 2 (assessment times) repeated measures analyses of variance. The three way interaction term of gender by condition by time was analyzed first. We then analyzed the condition x time interaction; collapsed across genders. A significant condition x time interaction indicates differences between intervention and control conditions over time. Effects reflecting changes over time across groups were noted as were gender differences collapsed across intervention groups and time. In order to account for the likelihood of a type 1 error, several precautionary steps were taken, including limiting outcome variables to number of sex partners and numbers of unprotected sex acts, and conducting post-hoc statistical correction tests.

Results

Preliminary Analyses

Participants were recruited from day and residential mental health treatment programs for the severely mentally ill in Miami-Dade County, Florida. The average age of the sample was 39.59 years (SD=10.42). Twenty-four percent of subjects were non-Hispanic whites, 55% of subjects were African American, 20% of subjects were Hispanic and 1% of subjects were of

other ethnic backgrounds. The average level of education was 11.47 years ($SD=2.64$) and 5.0% of subjects reported that they were married. In terms of primary psychiatric diagnoses, most people screened were characterized as suffering from major depressive disorder (21.2%), schizophrenia (15.7%), bipolar affective disorder (9.6%), and schizoaffective disorder (8.4%). The remainder of the sample experienced a range of disorders, including drug and alcohol dependence, non-specified mood disorders, and post-traumatic stress syndrome. For drug and alcohol use, most respondents identified cocaine (24.1%) and crack (21.3%) as the major substance problems, with 17.3% reporting dual drug and alcohol addiction and 14.5% reporting alcohol as the major problem. The substance most frequently used in the past 30 days was tobacco, used on an average of 21.26 days ($SD=13.3$). No significant differences in diagnoses or substance use between E-CB and HPC groups at baseline were noted.

Of 477 screened, 96 were excluded based on the following criteria: 36 participants denied use of any alcohol or drugs over the past six months; 3 participants did not meet mental illness criteria; 38 participants had residency and transportation difficulties, 5 participants could not speak English, and 14 participants were unable to participate in the assessment because of significant cognitive impairment. Seventy-nine of those screened were unavailable due to early study termination. Of the 302 remaining, 12 were eliminated because of failure to participate in the intake assessment. Of the remaining 290 subjects, 164 were assigned to the E-CB group and 126 to the HPC group. Forty individuals were lost to 6 month follow-up (24 of 164 or 14% in the E-CB group; 16 of 126 or 13% in the HPC group). E-CB and HPC groups did not differ in the percent followed (Chi Square (1, $N=290$)=2.30, $p=.315$). Those followed were compared with those lost to follow-up on intake demographic, social, psychiatric variables as well as on intake values of outcome variables. Those not followed reported a higher percentage of total sex acts unprotected (53% vs. 38%) ($t(1,276)=2.07$, $p=.04$), more reported serious lifetime anxiety (80% vs. 67%) (Chi Square (1, $N=290$)=9.58, $p=.048$) and serious depression (88% vs. 71%) (Chi Square (1, $N=290$) = 4.65, $p=.033$). An additional 28 (18 E-CB, 10 HPC) subjects had missing data at intake (11 on sex risk behavior) or follow-up (3 on sex risk behavior) outcome variables and were excluded from the final analysis.

A total of 222 subjects were included in the final repeated measures outcome analysis. Of these, 122 were in the E-CB group and 100 were in the HPC group. To determine the equivalence of E-CB and HPC groups based upon baseline information, we compared the E-CB and HPC groups on baseline demographic, social, psychiatric, and outcome variables listed in Table 1 using t-tests and chi-square tests. No significant differences were found (all $ps>.10$). The groups were also compared based upon number of intervention sessions attended. All participants attended at least 4 sessions; 72% of E-CB and 63% of HPC subjects attended all six sessions. The groups did not differ significantly in the proportion of sessions attended (Chi Square (5, $N=222$)=5.3, $p=.15$). Distributions of all of the criterion variables appeared normal, with the exception of proportion of unprotected sex acts and total number of sex partners last 3 months. Log10/Ln transformations were performed which resulted in distributions that did not deviate significantly from normal. Subsequent analyses were performed using transformed values. Non-transformed values are reported in table.

Findings—Intervention x gender x time and intervention x time effects were not significant for HIV Knowledge or Perceived Susceptibility (all p values $> .10$). A main effect for time of assessment ($F(1,235) = 9.01$, $p<.003$) reflects modest increases in knowledge across intervention and gender subgroups (see Table 1). A significant main effect for time of assessment ($F(1,235) = 10.32$, $p=.001$) revealed modest reductions in Perceived Susceptibility across intervention and gender subgroups. A significant time effect was found

reflecting substantial reductions in levels of HIV Anxiety across intervention and gender subgroups ($F(1,235) = 114.48, p < .001$).

For Condom Attitudes, women demonstrated more favorable attitudes than men across intervention conditions and assessment times ($F(1,235) = 6.26, p = .013$). Attitudes improved modestly across groups between intake and follow-up ($F(1,235) = 4.03, p = .046$).

There were significant intervention $\times$ gender $\times$ time ($F(1,203) = 4.17, p = .042$) and intervention $\times$ time ($F(1,203) = 7.10, p = .008$) effects for Intentions to Practice Safer Sex. Males in the E-CB group demonstrated an improvement in intentions while males in the HPC group decreased their level of intentions. In addition, within the E-CB group, males had greater improvements than females ($F(3,206) = 3.67, p = .013$). In the combined gender analysis, E-CB participants demonstrated more favorable changes in intentions than found in the HPC condition.

There was a significant intervention $\times$ gender $\times$ time effect for Condom Use Skills ($F(1,224) = 4.85, p = .029$). The intervention $\times$ time effect ($F(1,224) = 24.62, p < .001$) was also significant. Males in the E-CB group demonstrated significantly greater condom use skill improvement than did females in the E-CB group and both males and females in the HPC group ($F(3,227) = 10.51, p < .001$) (all p values $< .05$). Across gender subgroups, E-CB group members demonstrated significant improvement whereas HPC members revealed a modest decline in skills over time ($F(1,224) = 7.97, p = .005$). The only significant findings regarding Sexual Self-Efficacy were that women revealed modestly higher levels than did men ($F(1,235) = 5.48, p = .020$).

For number of unprotected vaginal sex acts, there were no intervention $\times$ gender $\times$ time, intervention $\times$ time, or gender effects (all p values $> .10$). There was a significant time effect demonstrating a reduction in number of unprotected vaginal sex acts from baseline to follow-up across gender and intervention groups ($F(1,235) = 3.95, p = .048$). Males in the E-CB group demonstrated a reduction in the proportion of vaginal sex acts unprotected at follow-up ($t = 2.65, df = 54, p = .01$). No significant changes were evident among females in the E-CB group ($t = .65, df = 76, p = .51$) or among either males ($t = .82, df = 56, p = .413$) or females ($t = .43, df = 49, p = .66$) in the HPC group. It is also noteworthy that, across intervention conditions, males demonstrated significantly greater reductions in unprotected vaginal sex acts than females ($F(1,218) = 5.70, p = .018$).

Discussion

Participants in both E-CB and HPC received the same information components of HIV risk reduction intervention and we hypothesized no differences between conditions – but substantial increases across conditions. Consistent with expectation, we did not find an intervention group effect – but did find a modest increase (from 72% to 76% of items correct) in knowledge regarding HIV transmission and risk reduction across groups. These findings contrast somewhat with those of Carey et al. who reported knowledge increases of 7 to 10% (resulting in correct responses of between 77% and 80%) among members of the HIV risk reduction intervention (4). Otto Salaj et al. (6) reported only 61% correct responses at baseline with significant improvements (of 10%) among men but not women in the HIV risk reduction group. The lack of more meaningful improvement in HIV-prevention knowledge in this vulnerable group across studies is a concern because knowledge of possible health benefits of safer practices (i.e., preventing HIV and other STDs) can influence the perceived cost-benefit ratio of prevention and thus, the likelihood of commitment to change (15). Perhaps greater attention should be given to increasing content

clarity and salience, and demonstrations of mastery through ongoing assessment of knowledge acquisition.

It is anticipated that prevention intervention will increase perceived susceptibility and anxiety in connection with risky practices among participants. Catania et al. (19) suggests that moderate anxiety regarding personal risk behavior should facilitate commitment to change. In the current study, however, we found small reductions in perceived susceptibility and moderate reductions in anxiety across groups that were not accompanied by parallel reductions in risk behavior. It may be that substantial numbers of participants learned that their behavior was not particularly risky and demonstrated reductions in perceived susceptibility and anxiety as a consequence.

We found modest improvement in personal and partner attitudes regarding condom use across groups and a trend toward greater improvement in the E-CB group than in the HPC group. However, we found no intervention or time linked changes in personal condom attitudes. Otto Salaj et al. (6) found a small magnitude time effect for condom attitudes and a trend towards greater improvement among HIV intervention group women than control women. Carey, et al. (4) demonstrated HIV prevention group linked improvement in condom attitudes. Across studies, condom attitudes have been somewhat favorable at baseline and intervention-linked gains, when identified, have been small.

Commitment or intention to reduce one's risk behavior and increase safer practices involves deciding whether a behavior can be changed and whether the benefits of change outweigh the costs (15). In the current investigation, men in the E-CB condition revealed improvements in behavioral intentions to engage in safer practices relative to women in the same condition and both men and women in the HPC control. Carey et al. (4) found the HIV prevention group demonstrated significantly greater increases in condom use intentions than participants in both substance use reduction and control groups. Otto Salaj et al. (6) found time of assessment linked improvements for both men and women with a trend toward greater improvement in intentions in HIV prevention relative to HPC comparison women. Developing a firm, stable commitment to enact safer practices is a complex process. It often involves deciding to give up pleasurable activities in order to adopt perhaps less pleasurable, but safer, alternatives. The findings, across studies, suggesting that targeted HIV prevention intervention may be effective in modifying condom use intentions among the SMI is of considerable interest. Change in behavioral intentions may be useful marker in the process of changing risk behavior in this vulnerable population.

E-CB focused on developing condom use skills and encouraging a sense of self-efficacy in negotiating consistent condom use and reinforcing self and partner for maintaining preventive behaviors over time (15). Parallel to findings regarding behavioral intentions, men in the E-CB condition revealed significantly greater gains in condom use skills than did women in the E-CB condition and both men and women in the HPC condition. Men and women in the E-CB condition revealed improved skills at follow-up whereas in the HPC group both men and women showed a trend toward skill decline. E-CB male participants showed a 20% improvement (51% to 71%) in skills relating to condom use. However, changes in self-efficacy were not found. Participants reported moderately favorable sexual self-efficacy with women revealing modestly higher levels than men. Improvements in self-efficacy may be difficult to achieve among those with SMI over the course of brief intervention.

Neither intervention nor intervention x gender analyses revealed significant differences at follow-up in major risk behavior outcomes including total numbers of unprotected vaginal sex acts, proportions of vaginal sex acts unprotected, or number of sexual partners.

However, intervention x gender x time analysis revealed a trend suggesting that males in the E-CB group demonstrated a meaningfully greater reduction in the proportion of unprotected vaginal sex at follow-up than E-CB condition females and both males and females in the HPC condition. The possibility of an advantageous response to small group HIV prevention intervention on the part of men is of interest because it contrasts with findings in previous studies involving those with SMI (4, 6). In the current investigation, men in the E-CB group reduced the proportion of unprotected sexual occasions by more than 60% on average (from 34% to 13%) in comparison with a 17% reduction (from 29% to 24%) among men in the HPC condition. Women did not show meaningful reduction in either condition. Others have found that SMI women have benefited more than men from small group HIV prevention intervention (4, 6). Carey suggested that because women are more likely to become infected through heterosexual intercourse and perceive HIV as a greater health risk than do men, they may profit more from the interpersonal and self management components of the intervention. Otto Salaj et al. (6) found that women in a group HIV prevention intervention substantially increased both condom protected intercourse occasions and proportions of condom protected intercourse (from 20% to > 40%) relative to women participating in a health promotion comparison whom showed a decline in protected intercourse. We found moderate reductions in instances of unprotected vaginal sex acts across intervention and gender groups. A more careful examination of gender specific response to sex risk reduction intervention is warranted. For example, it is possible that exposure to trauma, extent of substance use, and negative affect (29) moderate the relationship between gender and HIV-TRR and sex risk outcomes among SMI.

We found no significant gender x intervention, intervention, or time linked reductions in number of partners. In contrast, Carey et al. (4) found significant IMB - HIV prevention group reductions in number of sexual partners and casual sex partners over a similar 6 month follow-up interval. Otto Salaj et al. (6) reported a decrease in number of sex partners among HIV prevention group women and an increase in number of partners among HPC group men over follow-up. Because most individuals with SMI do not report a large number of sex partners, it is difficult to demonstrate substantial reductions in group averages. However, even the rather small intervention linked reductions reported by Carey et al. (4) may be important when partners come from high risk groups. It might be useful to focus on the relatively small subset of individuals who engage in distinctively high levels of risk behavior (i.e., trading sex, sex or needle sharing with IV drug users, multiple casual partners). In the current investigation, over 90% reported two or fewer partners and more than 80% either 1 or no partner. However, a small subgroup revealed very elevated levels of risk behavior and little is known about intervention efficacy in this subgroup.

There are many conceivable reasons that an intervention may not have lead to significant reductions in sexual risk behaviors. Among the most important of these are the IMB components included in the intervention, severity of psychopathologies, and the strength of the Health Promotion comparison. Each of these issues is addressed below.

Although the intervention included many components that had proven successful in previous studies, we attempted to culturally adapt these for our target population. For example, we adapted a few exercises to better represent the target populations in our area, and removed content on drug dealing because that is not a problem among the SMI population sampled in our community. The changes necessary to adapt the curriculum for our populations were relatively minor and largely unrelated to HIV/AIDS. The only changes related to issues about sexuality were the expansion of basic STI and HIV information, updates (e.g., available methods of contraception), a few changes to material related to sexual assaults, and some wording changes to make the curriculum more inclusive of men and women. We do not think the minor changes we made in the intervention or lack of adherence account for

the results. Because there is little research on the essential components of HIV prevention interventions, we do not know what components are essential to retain effectiveness. This is an area worthy of continued research.

Secondly, our SMI patients may have been more severely disturbed than those in other studies and more focus on co-morbidity symptom in addition to teaching them HIV prevention skill may have been helpful. Studies have increasingly shown that the severity of psychopathology may interfere and the intervention might be more success of the intervention was due in part to the fact that friends reinforced the intervention content. Retrospectively, we determined that we may not have had completely reliable information on the nature or severity of psychopathology among study participants: though we gathered DSM diagnoses from participant chart review, we did not confirm the diagnoses with our own assessments, so must rely on the accuracy of the individual charts. Carey et al. found that those with less severe psychopathology responded more favorably to an IMB focused intervention in improving safer sex communication and reducing unprotected vaginal sex than those with more severe disorders (4). It is possible that participants in the current study had levels of psychopathology more comparable to Carey's non-responder group.

Finally, our control sessions differed from the controls of others HIV prevention studies for SMI, in which the control group watched videos and films about AIDS prevention. We chose not to do this as we wished to control for attention and non-specific effects by making the Health Promotion control group sessions the same number and length as the intervention group sessions and equally interesting. These sessions contained most health promotion information with minimal AIDS prevention or sexuality information. Participants' ratings of the two interventions (not presented) suggest that we succeeded in making the control group equally interesting. It is conceivable that the attention-matched control group facilitates having SMI patients focus on their future health, which, in turn, may have reduced their risk behavior. We believe that our design represents a methodological improvement over that used in many previous studies, but it is possible that non-specific factors are responsible for the apparent effects of many effective interventions.

Limitations

The results of this investigation should be considered in light of several important limitations. Major sex risk outcomes were measured by self report which may have been associated with either intentional misrepresentation or unreliability due to the psychiatric status of participants. However, we took a number of steps to reduce bias and enhance reliability and validity of reports. For example, participants were informed that their responses would be considered confidential and would not be shared with treatment providers or others. Timeline follow-back procedures were used to facilitate accurate recall. It would have been desirable to obtain biological measures of new STIs and to conduct partner interviews to assist in establishing the validity of self-reports. These approaches were not adopted because of challenges linked with gaining the cooperation of participating health providers and obtaining informed consent from participants for partner contact. Carey et al. (4) found that the IMB-HIV intervention revealed limited benefits among those with psychotic diagnoses. We did not have sufficiently reliable information about participant diagnoses to permit examination of psychiatric severity as a moderator of intervention effects. All participants were recruited from programs focusing on treatment of the seriously mentally ill.

Another significant limitation is that our follow-up period was restricted to six months. Ideally, investigations of intervention effects should be extended over longer intervals. Although we found few differences between those who attended the intervention and

follow-up assessment sessions and those lost to follow-up, several are worthy of note. A higher percentage of total unprotected sex acts, more lifetime anxiety and serious depression among those lost to follow-up might have influenced the pattern of intervention outcomes. The smaller percentage of unprotected sex acts among those followed might have reduced opportunities to detect treatment linked improvements on this outcome. On the other hand, the greater history of lifetime anxiety and depression among dropouts might have eliminated a group with reduced prospects for treatment response. Thus, although we are reasonably confident that such biases are unlikely to have substantially distorted our findings, we recommend caution in assuming our findings generalize to the larger population from which our sample was drawn.

References

2. Rosenberg SD, Goodman LA, Osher FC, Swartz MS, Essock SM, Butterfield MI, Constantine NT, Wolford GL, Salyers MP. Prevalence of HIV, hepatitis B, and hepatitis C in people with severe mental illness. *Am J Public Health*. 2001; 91(1):31–37. [PubMed: 11189820]
3. Senn TE, Carey MP. HIV, STD, and Sexual Risk Reduction for Individuals with a Severe Mental Illness: Review of the Intervention Literature. *Curr Psychiatry Rev*. 2008; 4(2):87–100. [PubMed: 18584060]
4. Kalichman SC, Kelly JA, Johnson R, Bulto M. Factors associated with risk for HIV infection among chronic mentally ill adults. *Am J Psychiat*. 1994; 151:221–227. [PubMed: 8296893]
5. Carey MP, Carey KB, Maisto SA, Gordon CM, Schroder KEE, Varnable PA. Reducing HIV risk behavior among adults receiving outpatient psychiatric treatment: results from a randomized controlled trial. *J Consult Clin Psychol*. 2004; 72(2):252–268. [PubMed: 15065959]
6. Meade CS, Sikkema KJ. HIV risk behavior among adults with severe mental illness: A systematic review. *Clin Psychol Rev*. 2005; 25:433–457. [PubMed: 15914265]
7. Otto-Salaj LL, Kelly JA, Stevenson LY, Hoffmann R, Kalichman SC. Outcomes of a randomized small-group HIV prevention intervention trial for people with serious mental illness. *Community Ment Hlth J*. 2001; 37:123–144.
8. Kelly JA. HIV risk reduction interventions for persons with severe mental illness. *Clin Psychol Rev*. 1997; 17(3):293–309. [PubMed: 9160178]
9. Fisher JD, Fisher WA. Changing AIDS-risk behavior. *Psychol Bull*. 1992; 111:455–474. [PubMed: 1594721]
10. Kaplan, M.; Herman, R.; Cournos, F.; McKinnon, K. HIV Prevention for People with Mental Illness, A Training Manual for Mental Health Professionals. 4. Columbia, NY: 1996.
11. Sitharthan T, Kavanagh DJ. Role of self-efficacy in predicting outcomes from a programme for controlled drinking. *Drug Alcohol Depend*. 1991; 27(1):87–94. [PubMed: 2029863]
12. Miller, WR.; Zweben, A.; DeClemente, C.; Rychtarik, RG. Motivational Enhancement Therapy Manual. Vol. 2. National Institute on Alcoholism and Alcohol Abuse; 1994. p. 1-120.
13. Drake RE, Bartels SJ, Teague GB, Noordsy DL, Clark RE. Treatment of substance abuse in severely mentally ill patients. *J Nerv Ment Dis*. 1993; 181(10):606–11. [PubMed: 8105026]
14. Drake RE, Mueser KT, Clark RE, Wallach MA. The course, treatment, and outcome of substance disorder in persons with severe mental illness. *Am J Orthopsychiatry*. 1996; 66(1):42–51. [PubMed: 8720640]
15. Mueser KT, Doonan R, Penn DL, Blanchard JJ, Bellack AS, Nishith P, DeLeon J. Emotion recognition and social competence in chronic schizophrenia. *J Abnorm Psychol*. 1996; 105(2): 271–275. [PubMed: 8723008]
16. Fisher, JD.; Fisher, WA. Theoretical approaches to individual level change in HIV risk behavior. In: Peterson, JL.; DiClemente, RJ., editors. *Handbook of HIV Prevention*. NY, NY: Kluwer Academic/Plenum Publishers; 2000.
17. American Psychiatric Association. *Diagnostic and statistical manual of mental disorders*. 4. Washington, DC: 1994.

18. Currie SR, el-Guebaly N, Coulson B. Factor validation of the addiction severity index scale structure in persons with concurrent disorders. *Psychol Assessment*. 2004; 16(3):326–329.
19. St Lawrence JS, Jefferson KW, Alleyne E, Brasfield TL. Comparison of education versus behavioral skills training interventions in lowering sexual HIV-risk behavior of substance dependent adolescents. *J Consult Clin Psychol*. 1995; 63:154–157. [PubMed: 7896983]
20. Catania JA, Kegeles SM, Coates TJ. Towards an understanding of risk behavior: An AIDS risk reduction model (ARRM). *Health Educ Behav*. 1990; 17(1):53–72.
21. Sorensen, JL.; London, J.; Morales, E. Group counseling to prevent AIDS. In: Sorensen, JL.; Wermuth, LA.; Gibson, DR.; Choi, K.; Guydish, JR.; Batki, SL., editors. *Preventing AIDS in Drug Users and their Sexual Partners*. New York: Guilford; 1991. p. 99-115.
22. Jemmott JB, Jemmott LS, Fong GT. Reductions in HIV risk associated sexual behaviors among black male adolescents: Effects of an AIDS prevention intervention. *Am J Public Health*. 1992; 82:372–377. [PubMed: 1536352]
23. McMahon RC, Malow RM, Jennings TE. Personality, stress and social support in HIV risk prediction. *AIDS Behav*. 2000; 4:399–410.
24. McMahon RC, Malow RM, Penedo FJ. Substance abuse problems, psychiatric severity, and HIV risk in Millon Clinical Multiaxial Inventory-II personality subgroups. *Psychol Addict Behav*. 1998; 12:3–13.
25. Gibson, DR.; Lovelle-Drache, J.; Young, MT.; Chesney, M. HIV risk linked to psychopathology in IV drug users. *International Conference on AIDS*; 1992. (Abstract POC 4691)
26. Branch, CR., editor. *National Institute on Drug Abuse. Risk Behavior Assessment*. Rockville, MD: 1991.
27. Needle R, Fisher DG, Weatherby N. Reliability of self-reported HIV risk behaviors of drug users. *Psychol Addict Behav*. 1995; 9:242–250.
28. Devieux JG, Malow R, Lerner BG, Dyer JG, Baptista L, Lucenko B, Kalichman S. Triple jeopardy for HIV: Substance using severely mentally ill adults. *J Prev Interv Community*. 2007; 33(1–2):5–18. [PubMed: 17298927]
29. Rotheram-Borus MJ, Koopman C, Haignere C, Davies M. Reducing HIV sexual risk behaviors among runaway adolescents. *JAMA*. 1991; 266(9):1237–41. [PubMed: 1870249]
30. Gil-Rivas V, Prause JA, Grella CE. Substance use after residential treatment among individuals with co-occurring disorders: The role of anxiety/depressive symptoms and trauma exposure. *Psychol Addict Behav*. 2009; 23:303–314. [PubMed: 19586147]

Table 1

Outcome Means and Standard Deviations by Intervention Group

	HPC Group		E-CB Intervention Group		HPC Group		E-CB Intervention Group	
	Baseline Mean (SD)		Baseline Mean (SD)		Follow-up Mean (SD)		Follow-up Mean (SD)	
HIV Knowledge ¹	Males	12.93-3.28	Males	13.58-2.76	Males	13.5-2.99	Males	14.18-2.54
	Females	13.3-2.82	Females	12.81-2.98	Females	13.2-3.02	Females	13.69-3.1
	Total	13-3.12	Total	13.13-2.96	Total	13.25-3.03	Total	13.92-2.93
Perceived Susceptibility ²	Males	2.54-0.58	Males	2.41-0.64	Males	2.42-0.69	Males	2.21-0.64
	Females	2.54-0.63	Females	2.63-0.62	Females	2.44-0.6	Females	2.44-0.7
	Total	2.54-0.6	Total	2.56-0.65	Total	2.42-0.65	Total	2.35-0.67
AIDS-related Anxiety ²	Males	3.08-0.76	Males	2.84-0.71	Males	2.99-0.74	Males	2.75-0.75
	Females	3.15-0.72	Females	3.09-0.77	Females	2.93-0.74	Females	2.85-0.71
	Total	3.12-0.76	Total	2.99-0.76	Total	2.95-0.74	Total	2.81-0.73
Personal Condom Attitudes ²	Males	3.17-0.44	Males	3.11-0.42	Males	3.17-0.43	Males	3.18-0.37
	Females	3.35-0.44	Females	3.27-0.41	Females	3.27-0.4	Females	3.23-0.39
	Total	3.25-0.43	Total	3.22-0.42	Total	3.21-0.42	Total	3.21-0.38
Peer and Partner Sexual Attitudes ³	Males	4-0.65	Males	4.03-0.71	Males	4.16-0.79	Males	4.32-0.66
	Females	4.12-0.65	Females	4.14-0.62	Females	4-0.87	Females	4.37-1.42
	Total	4.06-0.65	Total	4.12-0.67	Total	4.08-0.85	Total	4.36-1.19
Condom Use Skills ⁴	Males	4.89-1.82	Males	4.57-1.82	Males	4.56-2.09	Males	6.36-1.6
	Females	5.23-1.66	Females	5.2-1.87	Females	4.99-1.81	Females	5.77-1.95
	Total	5.05-1.74	Total	4.94-1.86	Total	4.76-1.97	Total	6.02-1.83
Sexual Self-Efficacy ²	Males	3.03-0.5	Males	2.94-0.5	Males	3.06-0.51	Males	2.91-0.51
	Females	3.19-0.52	Females	3.02-0.46	Females	3.21-0.54	Females	3.06-0.55
	Total	3.1-0.5	Total	2.98-0.48	Total	3.12-0.53	Total	3.01-0.53
Total Number of Unprotected Vaginal Sex Acts ⁵	Males	7.91-17.9	Males	6.75-17.63	Males	9.09-21.44	Males	2.55-4.95
	Females	12.04-22.5	Females	12.49-17.57	Females	5.42-9.44	Females	8.27-14.06

	HPC Group		E-CB Intervention Group		HPC Group		E-CB Intervention Group	
	Baseline Mean (SD)		Baseline Mean (SD)		Follow-up Mean (SD)		Follow-up Mean (SD)	
	Total	9.82–20.2	Total	10.13–17.75	Total	7.37–16.96	Total	5.89–11.53
Proportion of Unprotected Vaginal Sex Acts	Males	28.81–42.8	Males	33.89–45.64	Males	23.81–40.25	Males	12.91–31.68
	Females	29.97–41.1	Females	31.85–40.66	Females	26.41–38.45	Females	30.44–41.37
	Total	29.35–41.7	Total	32.7–42.65	Total	25.02–39.25	Total	23.19–38.52
Total Number of Sex Partners ⁵	Males	1.47–2.26	Males	1.84–2.79	Males	1.05–1.44	Males	0.82–1.25
	Females	2.4–5.39	Females	3.55–8.77	Females	0.9–0.97	Females	1.96–5.34
	Total	1.89–4.11	Total	2.83–6.95	Total	0.98–1.24	Total	1.48–4.17

¹ **Knowledge** about HIV Transmission was assessed using an 18 item true/false questionnaire. Participants received one point for each correct answer.

² **Susceptibility, Anxiety, Self Efficacy, and Condom Attitudes** scales have 4-point formats with response options ranging from “strongly disagree” (1) to “strongly agree” (4).

³ **Sexual Attitudes** scale has a 5-point Likert format with response options ranging from “extremely unimportant” [1] to “extremely important” [5] and yields a mean score with a possible range of 1–5.

⁴ **Condom use skills** were assessed by rating the participant’s ability to properly enact nine steps in correctly placing a condom on a penis model. Scores reflect the total number of correct steps.

⁵ Reporting interval for intake was last 3 months and for follow-up last 2 months.

Table 2

Diagram detailing sample sizes at each stage of study