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Examination of an interventionist-led HIV intervention among criminal justice-involved female prisoners

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Abstract

The purpose of this study was to examine the implementation, adherence and protocol fidelity for the Reducing Risky Relationships for HIV (RRR-HIV) study. The RRR-HIV study is a phase III trial of a randomized intervention to reduce human immunodeficiency virus (HIV) risk behaviors among incarcerated women in four US states: Connecticut, Delaware, Kentucky and Rhode Island. The intervention consists of five interventionist-led prison-based group sessions and a sixth individual community-based session. Data on adherence, implementation, acceptability and fidelity of the intervention were obtained from forms completed after the five prison-based sessions by both the interventionist and participant. Data from the sixth session were collected by the interventionist. Of the 363 women recruited to date, 173 (47.6%) have been randomly allocated to the experimental RRR intervention, of which implementation measures were available for 162 (93.6%). Almost three-quarters of women attended all five sessions, each of which lasted a median of 90 minutes, indicating successful implementation of the protocol across multiple study sites. Interventionists and participants alike reported that all of the topics for each session were discussed, suggesting adherence to the protocol. In addition, protocol interventionists indicated that more than 95% of the women were engaged/involved, interested, and understood the materials presented, indicating high levels of acceptability among the participants and fidelity to the intervention protocols. The majority of participants also answered all of the post-test questions correctly, which is another strong indicator of the fidelity to the intervention. Results suggest that the RRR-HIV study has been successfully implemented across multiple study sites. Adherence to the protocol, as well as protocol fidelity and acceptability, were also strong, which is essential to establish prior to examining outcome data.

Keywords

HIV; Intervention; Women offenders

1 Introduction

The rate of human immunodeficiency virus (HIV) infection is approximately 15-times higher among women offenders than among women in the general US population (De Groot and Cu Uvin 2005). In 2003, 2.8% of all female inmates were known to be infected with HIV, with lower rates among men (1.9%) (Bureau of Justice Statistics 2005a). Since a higher proportion of female prisoners are incarcerated for drug crimes than male prisoners (Bureau of Justice Statistics 2005b), drug-using behaviors that increase risks for HIV are especially troublesome for women. While sex exchange has been identified as an increased risk factor for HIV among female offenders (Cotten-Oldenburg et al. 1997), other consistently reported behaviors that increase a female offender's risk for HIV include sharing drug injection equipment, engaging in unprotected sex with drug-injecting partners, having sex with multiple partners, reporting a history of a diagnosed sexually transmitted infection (STI), inconsistently using condoms with multiple sex partners, and using alcohol and other non-injection drugs (Cotten-Oldenburg et al. 1999; Hankins et al. 1994). Since HIV infection among female inmates is a serious public health concern, a better understanding of factors associated with implementing and conducting targeted HIV interventions is needed, as well as documentation of approaches to ensure adherence and fidelity to these types of interventions. This was the purpose of our study.

Gender-specific HIV prevention interventions have been developed for drug-abusing women offenders (El-Bassel et al. 1997; Flanigan et al. 1996; Vigilante et al. 1999; Wechsberg et al. 1998). These interventions incorporate skill-building approaches for using condoms, negotiating condom use, and practicing safer sex (Schilling et al. 1991) and have shown promising results. For example, one study found that women who were more comfortable talking to their partners about condom use were also 2.4-times more likely to change their risky sexual behavior (Schilling et al. 1993). However, Schilling and colleagues identified barriers to behavior change, which were associated with beliefs, or what the Reducing Risky

Relationships-HIV (RRR-HIV) study calls “thinking myths”, including the belief that getting HIV is related to luck and that “one’s partner would become upset if asked to use a condom” (Schilling et al. 1993). Several of these interventions relating to HIV and/or acquired immune deficiency syndrome (AIDS) incorporated partner relationships but did not target how women could recognize risky relationships thinking myths to make safer decisions to protect themselves. Examples of interventions tailored for women in prison include a social support/skill-building intervention with an AIDS information group (St Lawrence et al. 1997); a skill-building and protective behavior acquisition model (El-Bassel et al. 1997); and a social support service linkage discharge planning intervention (Vigilante et al. 1999). HIV interventions for women in prison have generally not targeted risky relationships as a factor for HIV-related behaviors—particularly risky drug use and risky sexual behavior. While those interventions have been associated with positive outcomes, literature on the development, implementation, adherence, and fidelity of the intervention approaches is limited.

1.1 Women offenders and risky relationships

Research suggests that risky relationships are common among female offenders and often contribute to female criminality. For example, studies have shown that incarcerated women report increased family and social relationship problems when compared with incarcerated men (Peters et al. 1997; Sheridan 1996). Many women prisoners also have complicated histories of emotional, sexual, and/or physical abuse, which have been associated with their criminal activities (Bond and Semaan 1996; Sheridan 1996). The literature stresses the importance of relationships to women and how relationships can increase the likelihood of a woman’s risky behaviors (Covington 1998). For example, Miller (1976) indicates that social networks and positive relationships are critical for the psychological development of women, shape a woman’s thinking patterns, and influence a woman’s behavior. Other studies have also shown that relationships within social networks can influence risky sexual and drug use behaviors among female substance users (Miller and Neaigus 2001). Few interventions, however, have been developed that target these relationships, and even fewer explore issues related to the implementation of and adherence to such interventions.

The Reducing Risky Relationships for HIV intervention incorporates gender-specific assumptions from the relational model, developed by Jean Miller (1976), which indicates that women: “1) are affected by their relationships, both past and present, 2) develop a sense of self through these relationships, and 3) strive to maintain a sense of connectedness with others” (Finkelstein 1993). In other words, women connect in relationships and often engage in behaviors that are perceived to sustain and enhance relationships. Therefore, Miller’s relational model was selected because it suggests that relationships are critical for women and shape the way that women think. The theory suggests that women form their sense of identity through their relationships with others. This theoretical model was therefore chosen as the basis for the RRR-HIV intervention because few, if any, studies have examined women’s thinking about their relationships as a risk factor for HIV. Given the complicated relationship histories that are characterized by drug abuse, victimization, and violence, incarcerated women can develop flawed thinking patterns or ‘thinking myths’ about behaviors that are consistent with risky relationships and which place them in vulnerable positions for engaging in risky behaviors (Staton-Tindall et al. 2007). However, there is limited research to understand how risky relationships can influence a woman’s thinking, decision-making, and subsequent behavior.

1.2 The reducing risky relationships for HIV intervention

The RRR-HIV intervention was developed as part of the larger Criminal Justice Drug Abuse Treatment Studies (CJ-DATS) cooperative agreement (Staton-Tindall et al. 2007) and is currently being tested in an ongoing phase III trial. The intervention includes five group sessions in prison and one individual telephone or face-to-face session after community re-

entry. During phase I of the study, focus groups were convened in Kentucky and Delaware prisons and in the community to clarify substance-using women's HIV risk behavior, identify risky relationships, and understand better how women's thinking about relationships influences HIV risk behaviors (Staton-Tindall et al. 2007). Using focus group data, consultants, and an expert panel, we developed seven themes to ground the intervention, which were called risky relationship thinking myths. After pre-piloting, we worked with cooperating CJ-DATS research center partners to refine the intervention during phase II.

The risky relationship thinking myths used to develop the intervention were:

1. Having sex without protection will strengthen my relationship. (Fear of rejection)
2. I only think good things about myself when I am in a relationship, even if it is a risky relationship. (Self worth)
3. I can use drugs and always make healthy choices about protection. (Drug use)
4. I know my partner is safe by the way my partner looks, talks, and/or acts. (Safety)
5. I will not get HIV because I'm not really at risk. (Invincibility)
6. I've been with this partner for a long time so there's no need to practice safe sex. (Trust)
7. I have to use sex as a way to get what I want in a relationship. (Strategy/power)

The intervention targets these seven risky relationship thinking myths and incorporates gender-specific approaches that have been used with female drug abusers (Bartholomew et al. 2002; Najavits 1993) and incarcerated women (Covington 1998). The overall goal of the intervention is to make women aware of these myths and help them to make more informed decisions about the sexual relationships they engage in. The Reducing Risky Relationships HIV intervention fills a void with a targeted HIV intervention on risky relationships thinking myths for female drug-abusing prisoners re-entering the community.

The phase III intervention trial is testing the behavioral and attitudinal effects of the Reducing Risky Relationships intervention with criminal justice-involved female drug abusers re-entering the community in Kentucky, Rhode Island, Delaware, and Connecticut. The sites are testing the Reducing Risky Relationships intervention using a two-group design. Each site is randomly allocating participants into: (1) The Reducing Risky Relationships intervention group—five prison-based group intervention sessions, an HIV awareness videotape and a re-entry telephone or face-to-face community session that is scheduled to occur 30 days after community re-entry; or (2) The comparison group—an HIV awareness videotape. Hypotheses focus on examining differences between the two groups on attitudes, knowledge, and HIV risk behaviors, as well as secondary outcomes, at 30 days and 3 months after release.

This paper presents data from adherence and fidelity measures during the first year of implementation of the RRR-HIV study in order to examine intervention adherence and fidelity. Research and clinical literature on the adherence and fidelity of behavioral interventions for women that target HIV risk behavior is limited. An understanding of adherence and fidelity is critical for examining outcomes of the intervention. The approach used in psychotherapy research (Carroll and Rounsaville 1990) guided RRR-HIV project implementation and adherence to ensure a 'standard' dose of the intervention during the sessions. Critical to this approach is that (1) the intervention is specified in a manual; (2) interventionists are trained and clinically supervised to deliver the intervention as uniformly as possible, and (3) intervention delivery is monitored for ensuring quality control. Implementation, adherence, and fidelity measures have been developed and incorporated to monitor intervention dosage and are examined in this article. Delivery of a standard dose of the intervention is essential for

making unambiguous conclusions about efficacy. This behavioral trial incorporates this approach to ensure that a standard dose of the intervention is delivered. The intervention has been manualized, with session objectives, resources required for each session, information for the interventionist, suggested dialogue for the interventionist, and handouts clearly specified for each of the individual and group sessions. In addition, ensuring the fidelity and standardized implementation procedures of the Reducing Risky Relationships for HIV intervention is a priority in order to understand the context for and test outcomes.

In examining fidelity and adherence there is a range of methodological options, the most rigorous being videotaping and rating sessions using independent external coders. While perhaps the most sound, this method is also labor intensive and is ethically questionable for prison research in particular, since it decreases confidentiality. On the other end of the spectrum, having the interventionist rate the sessions potentially introduces self-report bias. Therefore, the RRR study incorporates several data sources, both individual and site specific, to measure implementation, for each of the participants who enter the intervention, by the number of sessions attended, length of time of each session, and measures of participant engagement in treatment. Measures completed by the interventionist are also used to assess adherence to the intervention manual. Finally, to address any potential biases introduced by relying on interventionist data alone, data were also collected from the participants after each session.

Adherence, for the purposes of the RRR-HIV study, refers to the degree to which the interventionists followed the intervention described in the manual. Fidelity refers to whether the implementation of the intervention was similar within sites (i.e., for the case where more than one interventionist was administering the intervention) as well as across sites. Implementation of the intervention is also discussed, as is the acceptability of the intervention as determined by both the interventionists and participants. The purpose of this article is to (1) present protocol adherence and fidelity measures, and (2) discuss adherence, implementation and acceptability findings for both interventionists and participants.

2 Methods

The RRR-HIV study is part of the National Institute on Drug Abuse, Criminal Justice Drug Abuse Treatment Studies (CJ-DATS) cooperative agreement (Wexler and Fletcher 2007). Participants included 336 women from correctional facilities in Connecticut, Delaware, Kentucky and Rhode Island. Women eligible for study participation included those who were at least 18 years of age, those scheduled to go before the parole board or serve out within 6 weeks of the targeted recruitment date, at least weekly substance use prior to incarceration, and willingness to participate. Those who had past month psychotic features, parole and/or probation conditions that would prohibit follow-up, or those unwilling to take part, were not eligible for study participation. From a monthly roster provided by prison staff, women who were approximately 6 weeks from their parole hearing or release date were sent letters asking them to attend a screening session. The purpose of the screening session was to provide information pertinent to study participation, answer questions and administer the screening instrument to women interested in participating. Those women meeting the study criteria were invited to participate in the RRR-HIV study and consented. Baseline data were collected face-to-face by a trained interviewer, and follow-up data were collected 30 days and 90 days after the women's release. The project was reviewed by each participating institutional review board at the four participating universities—University of Kentucky, Memorial Hospital of Rhode Island and The Miriam Hospital, University of Connecticut, and the University of Delaware.

2.1 Description of the intervention

The intervention consisted of five face-to-face group sessions that were conducted prior to the woman's release from prison and one telephone or face-to-face individual session upon release. Content of each of the sessions was as follows. Session 1 focused on facts about HIV and other blood-borne infections, such as hepatitis B and C. Specifically, the interventionist discussed sexual and drug-related transmission, condom use (both male and female), and HIV testing procedures. The women also practiced condom use on male anatomical models. Session 2 focused on the risky relationships thinking myth "I can use drugs and still make healthy choices". In this session the interventionist covered the similarities between falling in love, using substances and unhealthy risky relationships. Specifically, healthy and unhealthy relationships were discussed, in addition to development of a safety plan for not using drugs. In session 3, the thinking myths "Having sex without protection will strengthen my relationship" and "I only think good things about myself when I am in a relationship, even if it is a risky relationship" were introduced. The interventionist discussed abuse and control in this session and, specifically, how abuse could increase a woman's risk for HIV and other blood-borne infections (BBIs) and sexually transmitted infections (STIs). The women were also asked to think of ways that they could protect themselves from abuse without using substances. Session 4 covered three thinking myths: "I know my partner is safe by the way they look, talk and/or act"; "I've been with this sex partner for a long time so there's no need to practice safe sex"; and "I will not get HIV because I am not really at risk". The interventionist discussed the rights of women to protect themselves from HIV and other infectious diseases and taught the women effective communication skills for negotiating safer sex. In session 5, the focus was on the thinking myth "I have to use sex as a way to get what I want in a risky relationship". The interventionist discussed supportive relationships, when to call on people for support, and places to find new relationships. Finally, in session 6, the participants were contacted once they had transitioned back to the community. The purpose of this session was to help the women process what they had learned about decision making and HIV risk as part of the intervention. Each of the thinking myths was reintroduced. Throughout the session, the participants were asked to recall some of the key elements from each session. Then, the interventionist was asked to rate the extent to which the women were able to recall the information. Actual behaviors were measured as part of the 30-day follow-up questionnaire that was administered immediately following session 6 for those randomly allocated to the RRR group. Those in the control group also completed the same questionnaire but were not provided any additional information. At the 90-day follow-up, both the RRR and control groups were administered the same questionnaire to measure changes in behaviors, attitudes and knowledge.

2.2 Interventionist training

An intensive 2-day training session was held, in which the interventionists were taught to deliver the intervention effectively. This training included role-playing exercises and evaluation of intervention delivery. The interventionists and interviewers alike were also trained on human subjects issues, working with prison populations and safety in criminal justice settings, and tactics to facilitate group participation and manage difficult group members. All the interventionists had at least a bachelors degree, while the majority had a master's degree or higher. All of the interventionists had prior experience in the prison setting. In addition, the clinical supervisor for the interventionists held a doctorate in social work. Finally, the interventionists were trained on how to complete the adherence and fidelity forms. Prior to study implementation, site visits were made to provide additional training. Additional site visits were made on an as-needed basis. For example, one of the sites hired a new interventionist after the training had taken place at the lead center. In that case, an interventionist from the lead center and the Principal Investigator visited the site to provide training for that interventionist.

2.3 Measures

Implementation of and adherence to the Reducing Risky Relationships for HIV intervention were examined, using measures completed by both the interventionists and participants. Implementation and adherence measures were developed by the RRR-HIV research team in conjunction with an expert panel. A multi-phase process was used to develop the measures, which included reviewing the HIV intervention implementation and adherence literature and collaboratively developing measures which were tailored to the RRR-HIV intervention. The implementation and adherence measures were specific to the RRR-HIV intervention because they addressed changing thinking myths (Staton-Tindall et al. 2007). The interventionists were asked to complete three forms at the conclusion of each session, and the participants were asked to complete one form (Figs. 1, 2, 3 and 4). First, for the implementation measures form (Fig. 1), the interventionists recorded the date, length of the session and data specific to each participant on her engagement, interest, and understanding of the material, and whether the session had been interrupted. These data were aggregated and sent to the lead center at the conclusion of each intervention session and recorded on the implementation summary form (Fig. 2). Data specific to session attendance, length of sessions, and measure of engagement were examined quarterly to ensure protocol fidelity both within site and between sites. For the facilitator measures form, the interventionists were asked to indicate whether they were able to adhere to the session content contained in the manual. This form was completed at the conclusion of each session (Fig. 3). The facilitator measures were sent to the lead center at the conclusion of the intervention sessions and compiled in a database for analysis.

Client feedback measures (Fig. 4) were completed by each participant at the conclusion of each session and consisted of two parts. The first part had the participants rate the interventionists on the extent to which they had discussed specific content. This served as an indicator of adherence to the protocol. The second part of the measure consisted of true/false questions that assessed the participants' understanding of the material covered in the session. Like the data collected by the interventionist, the client feedback measures were sent to the lead center at the conclusion of the intervention sessions and compiled in a database for analysis. Finally, as part of session 6, the interventionist was asked to rate the extent to which the participant could recall specific content from the previous five sessions.

2.4 Variables

In order to assess implementation and adherence to the RRR-HIV protocol, we utilized several of the measures described above. First, attendance (yes/no) and length in minutes for sessions 1–5 was examined, using data collected from the implementation measures. Second, data reported by the interventionists for each client were explored. Specifically, the interventionists reported on three areas: (1) client involvement/engagement; (2) client interest in the session; and (3) client understanding of the session content by recording 1 (indicating involvement, interest or understanding) or 0 (lack of involvement/engagement, lack of interest and lack of understanding of session materials). Third, we examined adherence, using data collected from the client feedback measure. Specifically, clients were asked to what extent the interventionist had discussed specific content points for each session. The responses ranged from 1 (not at all) to 4 (a lot). In order for us to determine protocol adherence and successful implementation of the material, clients were asked a series of true/false questions related to the specific content for that session. We also examined exposure to the intervention, or dose. High dose was defined as attending all five prison-based sessions. Low dose was defined as attending fewer than five sessions. Finally, in order for us to assess the extent to which participants were able to recall the information presented in the five prison-based sessions, nine questions were asked, interspersed within session 6. An example of these questions is “To what extent could the participant give reasons why women commonly use drugs?” The responses to the questions were rated by the interventionist as “Not at all”, “Somewhat”, and “A lot”. The interventionists

were provided with examples of reasons that were consistent with the RRR intervention that would constitute a rating of “A lot” or “Somewhat”.

2.5 Statistical analyses

To determine session attendance, we divided the total number of women who attended the session by the number of women randomly allocated to the intervention. Chi-square analyses were also conducted to determine if there were differences in attendance by site. We calculated the median length of time for each session, as well as the interquartile range (IQR). Analysis of variance (ANOVA) was used to discern differences in session length between sites. For the adherence data (i.e., whether the interventionist had discussed specific topics), the proportion of women reporting 1 (not discussed at all), 2 (discussed very little), 3 (discussed somewhat), and 4 (discussed a lot) were calculated for each discussion point. These groups were further dichotomized so that ‘not discussed at all’ and ‘discussed very little’ were combined into one category and ‘discussed somewhat’ and ‘discussed a lot’ were also combined into the other category. To determine agreement between interventionist and participant reports of adherence to the RRR protocol, we calculated the percent agreement. To analyze the data for each session in which the interventionist reported on the clients’ engagement/involvement, interest and understanding, we summed all the affirmative responses and divided by the total number of possible responses. For the client true/false knowledge questions, we added up the total number of correct answers and divided by the number of questions for each session. This was compared across sites using the chi-square statistic. Finally, chi-square analyses and *t*-tests were utilized to compare those who had received the full dose of the intervention versus those who had received either a partial dose or no dose. All analyses were conducted using SPSS, version 15.0 (Chicago, IL, USA).

3 Results

Results are reported for 162 of the 173 (93.6%) women who were randomly allocated to the RRR-HIV protocol. The first 11 women who completed the intervention reported anonymously and were therefore excluded from the analysis. The protocol was changed so that, in subsequent sessions, the participant’s identification (ID) was linked with the client feedback measures so that we could measure outcomes.

Of those women randomly assigned to the intervention, 119 (73.5%) received the full dose of the intervention (i.e., attended all five prison-based sessions), whereas the remaining 26.5% of participants attended anywhere from no sessions to four sessions (i.e., low dose). When those receiving the full dose of the intervention were compared with those receiving the low dose, women who were younger were significantly less likely to attend all sessions (median age 28.4 years compared to 35.7 years for women attending all sessions, $P=0.006$) (Table 1). There were no differences by drug use category, site, sexual history or other sociodemographic characteristics. Session attendance was as follows: 85.8% of women randomly assigned to RRR attended session 1; 82.1% attended session 2; 77.8% attended session 3; 76.4% attended session 4, and 75.9% attended session 5. Almost three-quarters of clients (73.9%) attended all five sessions, and 90% of those who were released and subsequently followed-up were provided with session 6. The most common reasons provided for missing sessions included: release from prison or transfer to another prison, work, or dropping out of the intervention. There were no significant differences in session attendance by site. The 30-day and 90-day follow-up rates for both the intervention and control arms were 94% and 90%, respectively.

The anticipated length of each session was 90 minutes. The median length of time for session 1 was 90 minutes (IQR 85, 90 minutes), 90 minutes for session 2 (IQR 83, 90 minutes), 90 minutes for session 3 (IQR 85, 90 minutes), 90 minutes for session 4 (IQR: 86, 90 minutes)

and 93.5 minutes for session 5 (90, 104 minutes), and there were no differences in the session length by site.

As shown in Table 2, the interventionists indicated that the large majority of participants had been involved and engaged in each of the five sessions. In addition, nearly all participants seemed to understand the material in the five sessions. Finally, most participants also seemed to be interested in the material presented.

Table 3 demonstrates the percent agreement between the interventionist and participant reports of adherence to the RRR protocol. For example, in session 2, the interventionists were asked whether they had presented information relating to “The difference between healthy and unhealthy relationships”. The participants were then asked the extent to which the interventionists had presented information on “The difference between healthy and unhealthy relationships”. The agreement between the interventionists and the participants that “The difference between healthy and unhealthy relationships” had been discussed was 94.6%. In fact, the agreement between interventionists and participants on session content was at or above 90% for all sessions.

Data for session 6 are as follows. When women were asked the extent to which they could identify healthy and unhealthy characteristics of relationships, 65.4% could name ‘a lot’ of characteristics, 33.1% could name some, and only 1.5% could name none. The participants were then asked if they could give reasons why women commonly use drugs. Most (63.9%) could give a lot of reasons, while 34.6% could name some. The remainder (1.5%) could not name any. When queried to identify reasons why it is difficult to use drugs and make healthy choices, women were most likely to name a lot (62.4%) or some (36.8%). Only one person could not name any reasons (0.8%). Next, participants were asked to name reasons why they might not ask their partners to use protection. More than half (58.6%) reported a lot of reasons, 39.1% only reported some and three women (2.3%) could not name any reasons. After the content for session 4 had been reintroduced, participants were asked to identify the triggers for unprotected sex. Most (61.7%) could name several reasons, whereas 35.3% of the participants could name some. Only 3% of women could not identify any of the triggers of unprotected sex. When then asked by the interventionist to walk her through the decision-making process for not using protection with a long-term partner, most could “a lot” (54.9%) or “somewhat” (43.6%), whereas two women could not walk through this decision-making process. After discussing the thinking myth “I will not get HIV because I am not really at risk” that was part of session 4, the women were asked to identify personal reasons why they were/were not at risk for HIV or other sexually transmitted diseases (STDs). More than two-thirds of the women could name a lot of reasons, and all but one of the remainder of the women could name some reasons. Finally, after being reintroduced to the content of session 5, the women were asked the following: “Why does having multiple supportive relationships reduce a woman’s risk for having unprotected sex?” and “So, now that you’ve had some time to use what you’ve learned in the group, how do you feel about your ability to protect yourself from HIV and other STDs?” More than half (53.4%) could name a lot or some (39.1%) reasons about the importance of supportive relationships, while 61.7% felt confident about their ability to protect themselves from HIV.

We also examined protocol implementation using post-test measures that gauged the extent to which participants understood the material presented. For session 1, the majority of participants answered all five post-test questions related to HIV correctly (71.5%), while 24.1% answered four of five correctly. For session 2, 59.8% of the women answered all four post-intervention questions related to drug use and risky relationships correctly, and 37.9% answered three of four correctly. For session 3, which focused on abuse, 56.8% of women answered all four questions correctly, while 36% answered three correctly. Most of the participants in session 4

scored perfectly on the post-test questions (81.1%), while 13.8% answered four of five questions correctly. Finally, for session 5 there were three post-intervention questions posed to the participants: 81.3% answered all three correctly, and 15.4% answered two correctly. There were no significant differences in the proportion of women answering correctly across sites.

4 Discussion

Data collected by both the interventionists and the participants indicated that this randomized phase III trial has been successfully implemented across study sites. Further, it appears that there has been a high degree of adherence to the RRR-HIV protocol, which is essential for manualized interventions such as this (Carroll and Rounsaville 1990). Finally, there were few differences in protocol implementation by site, which suggests fidelity was also achieved across sites.

A strong indicator of protocol adherence was the length of time for each session. Results indicate that the median length of time for each session was similar for each session as well as across sessions, across all sites. In addition, the length of each session was in line with the anticipated session length of 90 minutes. Further, the interquartile range showed that there was little dispersion in the time taken to complete the sessions. Attendance at the sessions was also excellent; almost three-quarters of participants attended all five prison-based sessions, thereby receiving the full 'dose' of the intervention. This is in contrast to other gender-specific HIV interventions in which attendance has been historically low, with retention rates in the range of 47% to 78% for interventions with multiple sessions (Greenberg et al. 1998). The high retention and attendance rates for the RRR-HIV protocol can be attributed to several factors. First, focus groups were conducted with the target population of female inmates in order to ensure participant interest. Second, it has been shown that participants who engage with the interventionist have better outcomes (Prado et al. 2002), and these data consistently demonstrated participant engagement. Finally, the way in which the intervention was presented allowed the participants to be active participants and therefore more engaged, which likely also increased attendance rates.

Participants' high interest, involvement/engagement, and understanding of the session materials also point to successful implementation of the RRR-HIV protocol. The interventionists indicated that more than 95% of the participants had been engaged, interested, and had understood the material, which points to good adherence to the protocol by the interventionist. Studies indicate that participant interest and engagement in intervention studies are essential in changing targeted behaviors (Ball and Ross 1991; Simpson et al. 1995). Further, given the high levels of interest and engagement, these results indicate a strong alliance between the participants and the interventionist, which has also been shown to be important in successful implementation of interventions (Prado et al. 2002).

Findings from this examination of the implementation measures for the RRR-HIV indicate that the essential pieces of the intervention were presented to the participants, which, as noted by Kilbourne and colleagues (2007), is an important indicator of fidelity. More than 90% of the participants reported that the core materials for each session had been discussed by the interventionist "a lot" or "somewhat". Further, the agreement between the interventionists and participants, that the key issues for each session had been discussed, was excellent. These findings also speak for the effectiveness of the training of the interventionists in delivering the intervention in a similar fashion, as there were no differences in the client reports across sites.

Finally, the majority of participants answered all the post-test questions correctly. However, there were several questions that challenged the participants in the first three sessions. It is

unknown whether the women did not understand the content associated with the specific questions, or whether there was some confusion with regard to how the question was asked of the participants. To ensure continuity of the protocol, the content of the intervention will not be changed for the purposes of the current study. These results can, however, be used in the future to fine-tune the intervention and present the information to the participants more effectively.

Data consistently show that incarcerated women are at increased risk for HIV and other STD's (Cotten-Oldenburg et al. 1999; Hankins et al. 1994). However, few interventions have been developed for this population. Since most, if not all, of these high risk women will eventually transition back to the community, it appears that interventions such as RRR aimed at providing women with the tools necessary to make informed decisions about risky behaviors, are warranted. Given the findings presented here that show successful implementation of this intervention, RRR may be a viable option for reducing HIV risk among substance-abusing offenders re-entering the community.

4.1 Limitations

The following limitations should be noted. Specifically, the study participants were not a random sample of incarcerated women. Although not randomly selected, all women who were eligible for release could have self-selected for participation, since they were asked if they were interested in participating in the study. However, once women indicated that they were interested in participating, they were randomly assigned to either the RRR-HIV intervention or the control group, which thereby eliminated much of the potential selection bias. Also, adherence and fidelity data were largely based on the interventionists' perceptions of the clients' experiences in the groups, which has implications for the validity of the findings. Ideally, the intervention would have been evaluated by an outside party that took into account the experiences of the interventionist, participant and an outside observer. Future studies utilizing the RRR-HIV intervention would be greatly enhanced by using an outside evaluator to determine protocol adherence and fidelity. Finally, the validity and reliability of the instruments used to evaluate the intervention have not been demonstrated.

5 Conclusions

Despite these limitations, the results from this study show successful implementation of the RRR-HIV intervention. Key lessons learned in conducting the RRR-HIV intervention include the importance of refining the protocol within the target population, prior to implementation of the study in a large sample, and the continued training and clinical supervision of the interventionists. Few, if any, studies have focused on women's thinking myths as HIV prevention. Therefore, this study greatly adds to the literature as an intervention that can be successfully implemented in the prison setting, is well-attended by the female inmates, and increases knowledge surrounding relationships and HIV. This is important, given the dearth of HIV-related interventions for incarcerated substance-abusing women re-entering the community. Finally, given that protocol fidelity has been established, the study team can now determine the effectiveness of the intervention in reducing high risk HIV-related behaviors among women re-entering the community.

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Biography

Jennifer R. Havens has a Ph.D. in epidemiology as well as a Masters in Public Health (M.P.H.) from the Johns Hopkins School of Public Health. Her research interests include the epidemiology of prescription drug abuse, rural health disparities specific to substance use, and the infectious complications of injection drug use, namely HIV and hepatitis C. Dr. Havens is currently funded through the National Institutes of Health to examine social networks and HIV risk among rural drug users.

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Hannah K. Knudsen, Ph.D. is Assistant Professor in the Department of Behavioral Science and a faculty member in the Center on Drug and Alcohol Research at the University of Kentucky. Much of her research has explored the relationships between organizational factors and the delivery of health services within addiction treatment organizations. In addition, her research on the treatment workforce has examined how managerial practices and clinical supervision are associated with counselors' reports of burnout and turnover intention.

Jennifer Mooney, M.S. is a Project Director at the Center on Drug and Alcohol Research at the University of Kentucky where she is pursuing her Ph.D. in the Department of Sociology.

Her research interests include women and crime, substance misuse, incarceration, and HIV. Current research examines health disparities, substance use, and crime among African American women (PI: Oser, C.) and the systems-level integration of public health and safety for substance using offenders (PI: Leukefeld, C.).

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Hilary L. Surratt, Ph.D. is a Scientist with the Center for Drug and Alcohol Studies at the University of Delaware, and a Guest Professor in the Department of Psychiatry at the Federal University of Rio Grande do Sul in Porto Alegre, Brazil. She is currently the Principal Investigator of a NIDA-funded epidemiologic study among HIV positive substance abusers in Miami, Florida; the Co-Principal Investigator and Project Director of a case management intervention program for African American women at high risk for HIV, and a Co-Investigator on two other NIH-funded studies targeting prescription drug abuse and the diversion of prescription drugs to the illicit market. She has substantial experience with cross-cultural research, having previously served as a senior investigator on two HIV prevention/intervention initiatives in Brazil and the U.S. Virgin Islands. She has published widely in both English and foreign-language journals and other media in the areas of AIDS, substance abuse, drug diversion, and drug policy.

James A. Inciardi, Ph.D. is the Co-Director of the Center for Drug and Alcohol Studies at the University of Delaware; Professor in the Department of Sociology and Criminal Justice at Delaware; Adjunct Professor in the Department of Epidemiology and Public Health at the University of Miami School of Medicine; and a Guest Professor in the Department of Psychiatry at the Federal University of Rio Grande do Sul in Porto Alegre, Brazil. Dr. Inciardi's research career spans almost four decades, and includes numerous studies of substance abuse treatment among offender populations, HIV epidemiology and prevention, and prescription drug abuse and diversion. He is the author of more than 450 articles, chapters, and books in the areas of substance abuse, criminology, criminal justice, history, folklore, public policy, HIV/AIDS, medicine, and law.

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DIRECTIONS: The following is to be completed by the interventionist for each participant after each intervention session.

Site Number:

Interventionist:

Intervention Session #:

Date of Session
(MM/DD/YYYY):

 / /

Length of Session
(Minutes)

Please answer the questions below for each client. Record subject ID numbers in the column heading spaces. Responses are 0=NO, 1=YES

Subject ID #s →														
to be involved/ engaged?														
to be interested in the session topic?														
to understand the session's content and objectives?														
Was the intervention session interrupted? If YES- explain/describe:														

5. Is there anything else that you think is important to know about this respondent or her participation in this intervention session?

Fig. 1.
Implementation measures

Interventionist: _____

Site: _____

Date of Intervention Session 1: _____

Date of Intervention Session 5: _____

Summary:

	Session 1	Session 2	Session 3	Session 4	Session 5
Date of session					
Length of session (Minutes)					
% involved or engaged					
% interested in session topic					
% understanding content and objectives					
% of clients who had an interruption					

Fig. 2.
RRR implementation summary

Site Number:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Interventionist:	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Date of Session (MM/DD/YYYY):	<input type="text"/>	<input type="text"/>	/	<input type="text"/>
	<input type="text"/>	<input type="text"/>	/	<input type="text"/>
Length of Session (Minutes)	<input type="text"/>	<input type="text"/>	<input type="text"/>	
# of Participants	<input type="text"/>	<input type="text"/>		

DIRECTIONS: This page is to be completed by the interventionist for each session. During this session, did you . . .

	YES	NO
1. Introduce facts about HIV	1	0
2. Discuss the facts about HIV	1	0
3. Discuss Session Six which will occur in the community upon release	1	0
4. Did you encounter any difficulties conducting the activities planned for this session? If yes, please describe below.	1	0

Fig. 3.
Facilitator measures, session one: facts about HIV

CLIENT FEEDBACK MEASURES

What Did You Think?
Session One

DIRECTIONS: We hope you enjoyed today's session. To help us improve Session One, please answer the following questions about your experiences in today's group. For each question, circle the answer which best describes how much your group leader discussed each topic:

How much did your group leader discuss...

1. Thinking myths about HIV?			
(1) Not at all	(2) Very Little	(3) Somewhat	(4) A lot
2. How you get HIV, Hepatitis B, and Hepatitis C?			
(1) Not at all	(2) Very Little	(3) Somewhat	(4) A lot
3. Behaviors that increase your risk for getting HIV, Hepatitis B, and Hepatitis C?			
(1) Not at all	(2) Very Little	(3) Somewhat	(4) A lot
4. Using male and female condoms to reduce your risk for getting HIV, Hepatitis B, and Hepatitis C?			
(1) Not at all	(2) Very Little	(3) Somewhat	(4) A lot
5. The HIV testing process.			
(1) Not at all	(2) Very Little	(3) Somewhat	(4) A lot

DIRECTIONS: Please circle "true" or "false" to answer each question:

- There is a cure for HIV.
True False
- There is no vaccination for Hepatitis B.
True False
- If I inject drugs, I can get HIV through sharing cookers, cotton, and rinse water.
True False
- Crack and cocaine use can increase my risk for HIV, Hepatitis B, and Hepatitis C.
True False
- A female and a male condom should never be used at the same time.
True False

What was the most important thing you learned in today's session?

Fig. 4.
Client feedback measures

Table 1
Demographic characteristics, drug use, and baseline sexual behaviors among low/high dose participants (N=162)

Characteristic	High Dose (n=119)		Low Dose (n=43)		P
	(n)	(%)	(n)	(%)	
Race					
White	76	63.9	28	65.1	0.055
African American	37	31.1	9	20.9	
Hispanic	0	0	2	4.7	
Other race/ethnicity	6	5.0	4	9.3	
Age, median (interquartile range)	35.7 (28.1, 43.2) years		28.4 (23.6, 39.1) years		0.008
Marital status					
Married/cohabitating	16	13.4	5	11.6	0.953
Single, never married	59	49.6	22	51.2	
Separated/divorced	44	37.0	16	37.2	
Employment					
Full time	38	31.9	12	29.9	0.635
Part time	13	10.9	7	16.3	
Unemployed	68	57.1	24	55.8	
Study site					
Kentucky	75	63.0	30	69.8	0.132
Delaware	27	22.7	4	9.3	
Connecticut	17	14.3	9	20.9	
Daily substance use					
Alcohol	35	29.4	9	20.9	0.323
Marijuana	38	31.9	19	44.2	0.192
Crack	45	37.8	16	37.2	1.000
Cocaine	22	18.5	12	27.9	0.198
Heroin	12	10.1	5	11.6	0.776
Methamphetamine	5	4.2	1	2.3	1.000
Prescription opiates	28	23.5	16	37.2	0.109
Lifetime injection drug use	55	46.2	15	34.9	0.214

Characteristic	High Dose (n=119)		Low Dose (n=43)		P
	(n)	(%)	(n)	(%)	
Number of arrests, drugs, median (IQR)	7 (3, 16)		5 (2, 10)		0.185
Number of times in prison, median (IQR)	6 (3, 16)		5 (2, 11)		0.361
Number of lifetime arrests, median (IQR)	9 (5, 20)		6 (3, 15)		0.066
Age at first arrest, median (IQR)	19 (16, 27) years		18 (15, 25) years		0.337
Months in prison, median (IQR)	23 (12, 42)		20 (9, 48)		0.885
Unprotected sex (past 30 days)					
Any unprotected sex	95	79.8	36	83.7	0.657
While trading sex	27	22.7	9	20.9	1.000
With injection drug user	17	14.3	8	18.6	0.622
During vaginal sex	90	75.6	31	72.1	0.684
Not with primary partner	17	14.3	3	7.0	0.284

Table 2
Interventionist reports of client involvement, interest and understanding for RRR-HIV sessions

Session Content	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6
Participants involved/engaged	97.8%	98.5%	97.6%	98.4%	98.4%	97.0%
Participants interested in material	99.3%	99.3%	98.4%	100%	100%	97.0%
Participants understood material	98.6%	99.3%	100%	99.2%	97.6%	97.0%

Table 3
Percent agreement between interventionists and participants on session content (*HCV* hepatitis C virus, *HBV* hepatitis B virus)

Session Content	Interventionist		Participant		Percent Agree
	Yes	No	Yes	No	
Session 1					
Thinking myths about HIV	138	0	136	2	98.5%
Transmission of HIV, HCV, HBV	137	0	135	2	98.5%
Behaviors increase risk for HIV, HCV, HBV	137	0	134	3	97.8%
Use of male/female condoms to reduce risk	138	0	136	2	98.5%
HIV testing process	138	0	135	3	97.8%
Session 2					
Similarities between falling in love, using substances and unhealthy relationships	132	0	129	3	97.7%
Difference healthy unhealthy relationships	131	0	124	7	94.6%
Connection between drug use risky relationships	132	0	128	3	96.9%
Developing safety plan for not using drugs	132	0	130	2	98.5%
Session 3					
Different types of abuse	125	0	123	2	98.4%
Power and control keep from escaping abuse	125	0	123	2	98.4%
Cycle of violence	125	0	123	2	98.4%
Connection between abuse, substance abuse, risky sex	125	0	123	2	98.4%
Session 4					
Right of women to protect themselves sexually	122	0	122	0	100%
Relationship triggers engaging in unprotected sex	122	0	122	0	100%
Creating plan dealing with triggers for unprotected sex	122	0	122	0	100%
Effective communication to negotiate safer sex	121	0	121	0	100%
Session 5					
The importance of having support	123	0	122	1	99.2%
Areas of support women need leaving prison	123	0	122	1	99.2%
How to identify times when need support	112	9	122	1	91.0%
Places to find new relationships	123	0	121	2	98.4%