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**Criminal Justice Drug Abuse
Treatment Studies (CJDATS):
Restructuring Risky
Relationships-HIV (RRR-HIV),
2005-2008 [United States]**

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Alcohol Research*

Study Manual

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**Criminal Justice
Drug Abuse Treatment Studies**

**Restructuring Risky Relationships-HIV (RRR-
HIV): Study Data Manual**

Study Summary

Lead Center: **Center on Drug and Alcohol Research,
University of Kentucky**

Principal Investigator: **Carl Leukefeld**

Collaborating Research Centers:

**University of Delaware
CJDATS Coordinating Center**

Summary:

This project proposes to develop a manual driven intervention for criminal justice involved female drug abusers to examine its potential influence on reducing HIV risk behavior including risky sex and drug use.

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Brief Report:

Link to: [Brief Report for RRR](#)

Study Protocol:

Specific aims:

The overall aim of this project is to develop and evaluate a manual driven HIV intervention for criminal justice involved female drug abusers who are re-entering the community. The project will develop the intervention manual using focus groups, train/supervise interventionists, pilot the intervention, modify the manual, report results, and finalize the Cognitive Restructuring HIV Intervention for Females (CR-HIVF) manual. The intervention will focus on reducing HIV behaviors using approaches grounded in cognitive restructuring (changing criminal thinking errors) and the relationship model. The following specific aims will organize the project:

1. Develop a draft manual which incorporates a cognitive restructuring approach and a relational approach to target HIV related high-risk sexual behavior with five types of focus groups at each participating Research Center (RC) – (1) incarcerated women receiving in-prison drug abuse treatment, (2) recently released women who received in-prison drug abuse treatment and are receiving community treatment, (3) recently released women who did not receive in-prison treatment but are receiving community drug treatment, (4) prison based and community drug abuse treatment interventionists, and (5) correctional supervision officers.
2. Pilot the draft manual with three groups of 8 to 12 female prisoners receiving prison treatment (one group at each of the three participating RC's).
3. Refine the intervention manual based on the pilot test to target understanding the association between criminal thinking errors and relationships that lead to HIV related high risk sexual behaviors.
4. Develop interventionist training and supervision manuals as well as compliance measures to implement the manual driven intervention.
5. Evaluate the manualized intervention with a two group design – 1) prison sessions with 3 community re-entry follow-up sessions, and 2) prison sessions without community re-entry sessions -- with three month follow-up at each of the 3 participating RC's using a quasi-experimental design to examine differences between the two groups on risky sexual behavior, and criminal involvement and targeted drug use associated with risky sex between the two groups.

This project will contribute to CJ-DATS in several ways: (1) The intervention will fill a void by developing and evaluating a manual driven HIV intervention for incarcerated women who are re-entering the community; (2) The project will add to the literature on the unique issues of female drug abusing prisoners and HIV; and (3) The project will expand knowledge on understanding prison re-entry for female prisoners.

Although the primary outcome of the study will be HIV risks and related behaviors, the context of the study during the transitional re-entry phase targets the increased risks associated when women return to community. Consequently, the project targets re-entry for women since HIV risks are increased once women return to the community. This context will add to our better understanding of HIV risks and related service needs during the re-entry process, the linkage between the criminal justice system and the community, as well as changes in risk behaviors associated with community re-entry. Examining differences in risk behaviors during the transition from incarceration to community will also provide information about the use of community resources and the linkages between criminal justice and community services, which include community treatment, health services and HIV services. This study will assess the use of community re-entry services by examining differences between the two re-entry groups, including drug treatment and criminal justice “services”, which will add to a better understanding of system issues and barriers. Consequently, this study has the opportunity to enhance knowledge for community treatment providers working with women during the transition from prison to community. In addition, given the high number of women in community treatment who have criminal justice histories, and the likelihood of complicated relationships that accompany their substance use histories, this intervention may also be applicable for substance using women in community agencies.

Background and significance:

This section introduces research on female drug abusers in the criminal justice, the importance of HIV within this population, and efforts to address these issues through targeted gender-specific interventions for female drug abusers in order to establish a rationale for developing the Cognitive Restructuring HIV Intervention for Females (CR-HIVF).

Women in the criminal justice system

More than 97,000 women were incarcerated in state and federal prisons in 2002 with an increase of nearly 5% from 2001 (BJS, 2002). This increase represents a national trend since the number of incarcerated women more than doubled from 1990 through 2001 (BJS, 2002). Consequently, women represent the fastest growing group of prisoners, which has been associated with drug use and drug related offenses (Henderson, 1998). Specifically, about one of every three women is incarcerated on a drug-related offense, and about half of incarcerated women were under the influence of alcohol and/or drugs at the time of their criminal offense (BJS, 2000).

Female drug abusers involved in the criminal justice system have traditionally re-entered the community with probation and parole services (Leukefeld, Tims and Farabee, 2002). Although limited studies have shown that female drug abuse clients referred from the criminal justice system have positive community treatment outcomes (Polcin, 2001; Leukefeld, Tims & Farabee, 2002), few interventions have been developed for female criminal justice involved drug abusers (Covington, 1998; Pickens, Leukefeld & Schuster, 1991; Wanberg & Milkman, 1999; Zlotnick, Najavitis, Rohsenow, & Johnson, 2003) with little data to demonstrate effectiveness. In fact, even though female criminal justice clients represent a substantial

number of drug abuse clients returning to communities and to community drug abuse treatment, our review did not identify any interventions that were systematically developed, evaluated, and in manual form for female drug-involved prisoners re-entering the community.

Women, criminality, and relationships

Along with the increasing numbers of women prisoners, empirical work over the last decade has demonstrated that there are unique contributing factors to female criminality which include problem relationships. For example, studies have shown that incarcerated women report increased family and social problems when compared to incarcerated males (Sheridan, 1996; Peters, Strozier, Murrin, & Kearns, 1997). Women prisoners have complicated histories of emotional, sexual, and/or physical abuse, which not only characterize women prisoners but also may be related to their criminal activities (Bond & Semaan, 1996; Sheridan, 1996).

The literature focused on women stresses the importance of relationships and how these relationships can increase the likelihood of a woman engaging in problem behaviors. Gilligan (1982) indicates that networks and connections are critical for the psychological development of women. The extent to which these networks encourage or sustain problem behaviors have a role in the behavior. In fact, studies have shown that structural qualities of social networks can influence risky sexual and drug use behaviors among female substance users (Miller & Neaigus, 2001). Complicated gender relationships have also been associated with drug use, criminality, and high-risk sexual behavior. These findings contributed to the development of a framework to better understand the connections between relationships and problem behaviors known as the relational model. The relational model, which is a gender-specific approach grounded in women's experiences, stresses the importance of relationships and enhancing relationships to help substance abusing women change problem behaviors (Finkelstein & Piedade, 1993; Finkelstein, 1996; Covington & Surrey, 1997).

Incarcerated women and HIV

In general, the rate of HIV infection is about 6 times higher among male and female prisoners than in the general U.S. population (Brien, 1995; Maruschak, 1999). Specifically, 2.4 percent of Federal and State prison inmates were known to be infected with HIV; slightly lower rates (1.8 percent) were found among jail inmates and higher among females -- 4.2 percent of females versus 2.5 percent of males (Braithwaite, Hammett & Mayberry, 1996). Although we were unable to locate any recent female-specific HIV intervention studies during the community re-entry phase, the chronicity of most criminal careers supports the assumption that those offenders receiving community supervision will not differ significantly.

Out-of-treatment criminal justice-involved drug abusers are generally at higher risk of exposure to and acquiring HIV than their noncriminal justice-involved counterparts -- particularly by exchanging sex (Farabee, Leukefeld et al. 1997). Sex exchange has been specifically identified as an increased risk factor for HIV among female offenders (Cotton-Oldenburg et al., 1997). Other consistently reported HIV risk behaviors which 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, exchanging sex for money or drugs, reporting a history of a diagnosed STD, inconsistently using condom with multiple sex partners, and using alcohol and other non-injection drugs (Cotton-Oldenburg, Jordan, Martin, & Kupper, 1999; Hankins et al., 1994). Thus, HIV infection among female inmates is a serious health concern.

Relationships and HIV

The idea that relationships are important for women's HIV risk behavior and prevention interventions is not new to the research literature. In fact, attitudes toward condom use, negotiating condom use, and behavior change have been related to involvement with an intimate partner in HIV interventions that target women (Schilling, El-Bassel, Gilbert, & Schinke, 1991; Schilling, El-Bassel, Gilbert, & Glassman, 1993). One study demonstrated that women who were less comfortable talking to their partners about sex and those women who indicated that they would still have sex if their partners refused to wear a condom reported less overall condom use (Schilling, El-Bassel, Gilbert, & Schinke, 1991).

There have been consistent findings related to the link between HIV risk behaviors and being in a long-term committed relationship among both drug using women and community women. Research indicates that women in a methadone maintenance program who are not in committed relationships actually report more condom use compared to women in committed relationships (Schilling, El-Bassel, Gilbert, & Schinke, 1991). In addition, one study reported that single drug using women were 15 times more likely to report changes in sexual risk behavior compared to women in monogamous relationships (Schilling, El-Bassel, Gilbert, & Glassman, 1993). Morrill et al., (1996) also found that among a sample of community women, those who were not involved in an intimate relationship were 11 times more likely to maintain safe sexual behavior compared to women in committed relationships. Thus, being in a relationship may increase HIV risk behavior because a woman feels safe, may believe that being assertive could change risky behaviors, and unprotected sex may be a sign of trust between a woman and her partner that enhances the relationship (Morrill, et al., 1996). The literature also includes interventions which focus on changing relationships for female prisoners (Covington, 1998) as well as women in the community (Bartholomew, Chatham & Simpson, 2002). In addition, several HIV prevention interventions target women drug abusers (El Bassal, et al., 1997; Flanigan et al., 1996; Surratt & Inciardi, 2001; Vigilante et al., 1999; Wechsberg, Dennis, & Stevens, 1998). However, these interventions have not targeted HIV related high risk sexual behaviors in the context of relationships using a cognitive restructuring/ thinking errors approach.

Criminal thinking interventions

In 1941, Cleckley identified manipulative characteristics used by criminals (Cleckley, 1988) that were described with greater precision as thinking errors by Yochelson & Samenow (1976; 1977; 1986) and Samenow (1984; 1991; 1998) who published and modified their phenomenological research findings about criminals admitted to a forensic mental hospital. They described patterns and qualities of criminal thinking as well as thinking errors that emerged during clinical experiences with individuals being evaluated for competency to stand

trial or being treated in lieu of incarceration (Yochelson & Samenow, 1976; 1977). They also established a continuum of criminal thinking and a range of criminality patterns from responsible, normal ethical conduct to irresponsible, criminal conduct. Yochelson & Samenow (1976; 1977; 1986) and Samenow (1984; 1991; 1998) also defined a range of criminality that included non-arrestable, arrestable, and extreme criminality. Yochelson and Samenow stressed the importance of focusing on this continuum of criminality. Yochelson and Samenow (1976; 1977; 1986) and Samenow (1984; 1991; 1998) identified 16 criminal thinking errors, many of which have been modified and incorporated into the clinical literature (Wanberg & Milkman, 1997; Gorski, 1984; Leukefeld, Tims & Farabee, 2002).

Despite the use of criminal thinking errors in the clinical literature, limited activity has focused on their utility with female offenders (i.e., Walters & Elliott, 1999; Walters, Elliott, & Miscoll, 1998), particularly thinking errors in the context of relationships. For purposes of this study, criminal thinking errors will be operationalized using Yochelson & Samenow (1976; 1977; 1986) and Samenow (1984; 1991; 1998) definition as “automatic perceptions of self and the world” or cognitive distortions that influence behavior. The proposed intervention will build on the thinking errors that have been found clinically to be drug use and criminal behavior risk factors (see Beck, Freeman & Associates, 1990; Beck, Wright, Newman & Liese, 1993). The proposed intervention will identify how these thinking errors are most important in contributing to problem relationships for women, and incorporate them as cognitive restructuring to change HIV risk behavior including sex and drug use.

Criminal thinking and HIV

Our literature review did not identify any studies which focused on HIV/AIDS and the Cognitive Restructuring of Criminal Thinking Errors. However, Cognitive Restructuring has been examined in reducing HIV risks. For example, Johnson et al., (2002) incorporated Cognitive Restructuring in a brief HIV intervention to identify “cognitive barriers” and “irrational beliefs” which are associated with risky drug use and sex. Another skills building intervention incorporated Cognitive Restructuring to help participants identify situations that placed them at risk, to generate coping strategies, to cognitively review new coping strategies, and to think about consequences (Schilling et al, 1995). Each of these HIV/AIDS interventions successfully incorporated Cognitive Restructuring, but the interventions did not target Criminal Thinking Errors and did not focus on criminal justice clients and their high level of cognitive thinking errors (Yochelson & Samenow, 1976; 1977; 1986).

As noted above, the practice literature and our experiences indicate that this approach has been used in criminal justice settings to target criminal thinking (see, Wanberg & Milkman, 1999; Leukefeld, Godlaski & Clark, 1998) and in institutional settings (Samenow, 1984; 1991; 1998; Yochelson & Samenow, 1976; 1977; 1986). However, a validated intervention has not specifically been developed and tailored for female offenders and HIV.

Female Thinking Errors and HIV

Female thinking errors as related to HIV risk behavior have not been targeted in HIV cognitive restructuring interventions. Interventions which have been developed for women include skill-building approaches and include a focus on women’s thoughts about condom use

and their ability to negotiate condom use with their partners and their ability to actually engage in safer sex (i.e., Schilling, El-Bassel, Schinke, Gordon, & Nichols, 1991). In fact, one study reported that women who were more comfortable in talking to their partners about condom use were 2.4 times more likely to change risky sexual behavior (Schilling, El-Bassel, Gilbert, & Glassman, 1993). This study also reported that barriers to behavior change were associated with thinking errors which included the belief that getting HIV is related to “luck” and the belief that “one’s partner would become upset if asked to use a condom” (Schilling, El-Bassel, Gilbert, & Glassman, 1993). The perception of a partner’s risk may also be influenced by involvement in a relationship. Specifically, a strong desire to enhance intimacy in a relationship may override a women’s ability to accurately assess her partner’s risk (Morrill, et al., 1996). This desire to please a partner may be consistent with the notion that women adapt their sexual behavior – risky or not – depending on the nature of their relationships and their level of involvement with a partner (Morrill, et al., 1996). Thus, these studies highlight the importance of female thinking errors in underscoring HIV risk behaviors in the context of relationships.

Summary and focus of the current study

This project is presented to develop an intervention and evaluate the intervention to address women’s HIV risks as part of CJ-DATS by developing an intervention specifically for criminal justice involved female drug abusers who are re-entering the community. The proposed intervention will be developed, piloted, refined, and evaluated in prison settings and community re-entry. If results from the evaluation are promising, a trial is planned. The manual driven intervention will target three critical areas for female drug abusing prisoners re-entering the community: 1) Identifying personal female thinking errors, 2) Examining relationships with males, and 3) Understanding the association between the Cognitive Restructuring of thinking errors and male relationships which lead to HIV related high risk sexual behaviors.

The overall approach to be examined for the intervention is group sessions completed during the final weeks of drug abuse prison treatment (sessions focused on criminal thinking and male relationships as well as the NIDA HIV intervention) and followed-up at community re-entry with individual telephone sessions at three points in time -- first week, first month and third month after prison transition to the community. These times were selected because they have been identified as critical times for contact after treatment (Leukefeld, Tims & Platt, 2001).

Research Design and Methods:

Theory and Conceptual Approach

Several conceptual models and theories were considered as the foundation for the intervention which include: (1) The Health Beliefs Model (Rosenstock, Strecher, & Becker, 1994); (2) Theory of Reasoned Action (Fishbein & Middlestadt, 1989); (3) Social Cognitive Theory (Bandura, 1994); (4) AIDS Risk Reduction Model (Catania, Kegeles, & Coates, 1990); (5) Diffusion of Innovation (Dearing, Meyer, & Rogers (1994); (6) Harm Reduction (Brettelle,

1991); and (7) The Stages of Change Transtheoretical Model (Prochaska, DiClemente, & Norcross, 1992). Given the focus of the intervention on change when female offenders transition to the community, the Stages of Change Transtheoretical Model was selected for several reasons which include – being able to measure an individual’s stage of change to tailor the intervention and the ability to assess change over time.

The Transtheoretical Stages of Change Model was specifically selected because the HIV/AIDS intervention will focus on changing high-risk behaviors by incorporating the Cognitive Restructuring of specific thinking errors which will be identified in our focus groups. Cognitive Thought Mapping will be used to cognitively restructure specific thinking errors which, for example, could include decision making related to unprotected sex with multiple partners (Thinking Error 5). Cognitive Thought Mapping is a visual representation that has been used by drug abuse interventionists (Czuchry, Dansereau, Dees, & Simpson, 1995) and with probationers (Czuchry & Dansereau, 1998). The Cognitive Thought Mapping approach develops a map which is drawn by a drug interventionist to link nodes (visually represented as boxes) as feelings, thoughts, and actions with links (visually represented by lines) to show relationships on paper between nodes. For this project, the interventionist and participants will jointly complete structured and pre-formatted individual maps focused on changing problems associated with thinking errors in relationships and related HIV risk behaviors including drug use and sexual activity (see Leukefeld et al., 2002; 2003).

The Cognitive Restructuring of Criminal Thinking Errors approach will form the basis for the intervention. The Cognitive Restructuring practice framework postulates that both affect and behavior can be influenced by engaging clients in a process of developing, evaluating and testing assumptions for change which are related to key areas, including antisocial behavior such as drug abuse (Beck, Freeman & Associated, 1990). The intervention will incorporate the Cognitive Restructuring of Criminal Thinking with Cognitive Thought Mapping (Leukefeld et al., 2001). In order to tailor a gender-specific model, which is grounded in the Stages of Change and the Relational Model, the manual will also build on existing gender-specific approaches that have been used with female drug abusers (Bartholomew, Chatham, & Simpson, 2002) and incarcerated women (Covington, 1998) to focus on high risk sexual and drug use behaviors. The manualized intervention will fill a void as a tailored HIV intervention for criminal justice involved female drug abusers who are re-entering the community. This project will develop a brief HIV intervention to reduce risky sexual and drug use behaviors for females who are leaving prison and re-entering the community that addresses their unique gender specific needs related to problem relationships.

Project Design

Over three years, this project will develop and refine the intervention and pilot test the intervention across three participating Research Centers (RC’s). Developing the intervention will be consistent with a NIDA Stage I project and will include accepted approaches for intervention development described by Carroll (2000); Carroll et al., (2002); Linehan (2000); and NIDA (1996). Working with experienced criminal justice partners and research teams, the lead center will develop the intervention and evaluate it across 3 participating RC’s. While the focus of this project is on intervention development and feasibility rather than

effectiveness, established instrumentation will be used in a quasi-experimental pre/post test design to evaluate the intervention. Data collection, data management, and analyses will be carried out by the lead center.

The three year project is organized in three phases: Phase 1 – Focus group and manual development; Phase 2 -- Pilot testing and refinement; and Phase 3 – Evaluation.

PHASE 1 – FOCUS GROUPS AND MANUAL DEVELOPMENT

During Phase 1 of this three year project, five focus groups will be convened in each of the RC's with (1) incarcerated women receiving in-prison drug abuse treatment, (2) recently released women who received in-prison drug abuse treatment and are receiving community treatment, (3) recently released women who did not receive in-prison treatment but are receiving community drug treatment, (4) prison based and community drug abuse treatment interventionists, and (5) correctional supervision officers to develop the draft manual. Using content from the focus groups, participating RC's staff, corrections partners, and community treatment partners will develop a draft manual.

Developing the intervention

In the first six months of the first year, the project team will conduct at least five focus groups to develop the intervention. Focus groups will be used to prioritize the session content, highlight key relationship issues to include, and target the sexual risk taking behaviors for the intervention. Key topics for the intervention will include criminal thinking, HIV risk behaviors, and relationships.

Specifically, we will ask focus group participants to identify the specific Criminal Thinking Errors for Cognitive Restructuring which will be targeted for up to a possible five session intervention from the following Criminal Thinking Errors described by Loebig (2000) which are most relevant for intervention: (1) Closed Thinking, (2) Views self as a good person, (3) Lack of effort, (4) Lack of interest in responsible performance, (5) Poor decision making, (6) Fear of death/injury, (7) Compelling need for control, (8) Sees self as different than others, (9) No concept of the rights of others, (10) Fails to learn from experience, and (11) Uses criminal masks of nice, tough or manipulator. An analysis of focus group data will be used to identify themes, specific Criminal Thinking Errors to target, and the number of intervention sessions.

Carroll's (2000) approach to developing the intervention manual will be used. Each of the five group sessions will include an informal didactic presentation led by the interventionist who introduces the topic, presents selected issues related to targeted behavior, and encourages group interaction (sample sessions from the Rural HIV prevention intervention which used this process with Leukefeld PI: DA 11580 can be made available to reviewers upon request). The group sessions will target selected Thinking Error(s) using Cognitive Restructuring skills building exercises for each selected Thinking Error and the Relational Approaches developed by Barthomew et al., (2002) and Covington et al., (1998). An individual session will be considered after group session 1 to help personalize HIV Risks for Cognitive Restructuring.

The focus groups will be used to clarify thinking errors used in decisions related to relationships and risk behaviors associated with HIV. Focus groups will be convened to provide input about the intervention approach and the manual's content. One of the primary goals is to understand how the approach and method will be useful in addition to obtaining interventionists' and clients' opinions about the intervention content and method of delivery. The next step will involve correctional, community treatment, and research partners to consult on developing the initial draft manual. The structure of each session to present specific thinking errors will be developed using the following eight elements developed by Beck, Wright, Newman & Liese, (1993, p.97): (1) Setting the agenda; (2) Mood check; (3) Bridge from the last session; (4) Discussion of today's agenda items; (5) Socratic questioning; (6) Capsule summaries; (7) Home work assignments; and (8) Feedback.

A cognitive framework is the conceptual approach proposed to be considered in developing the intervention as an appropriate framework for the providing an intervention. With this framework, it is postulated that both affect and behavior can be effected by engaging clients in a process of evaluating and testing their basic assumptions related to key problem areas, including antisocial behavior like drug abuse (Beck, Freeman & Associates, 1990). This approach can be combined with the skills approaches with the goal of imparting specific information and/or skills using an educational approach which is action oriented. In addition, a cognitive and skills group approach in our experience is the best fit with the needs of the clients, the experiences of the investigators, and the literature (Beck, Wright, Newman, & Liese, 1993).

Rationale for Intensity and Duration

One of the more important features in developing the intervention is its independence from specific modalities. The focus of the approach is on thinking errors and relationships in reducing HIV risk behaviors. The intervention will be readily adaptable to inpatient/residential and other treatment environments. The frequency of treatment contact and duration or overall dose exposure could be examined in a Stage II project to determine if there are important differences in frequency and duration. Providing results from this Stage I project are promising, a Stage II project would be planned to test the intervention in a randomized trial and long-term outcome evaluation. This study would align with the targeted vision for the CJ-DATS continuation.

For this project, the therapy will be administered one-time per week over the course of 5 weeks during prison, followed by community telephone contacts in the re-entry group. This session duration and intensity is consistent with other HIV interventions which have demonstrated that brief sessions are as effective as long-term interventions in reducing HIV risk behaviors (i.e., Brown & Beschner, 1993).

Manual Content

The therapy manual will be developed using the following content outline, which is adapted from a general outline presented by Carroll & Nuro (2002). The proposed outline

recognizes that the focus on an initial pilot/initial evaluation to examine the feasibility and efficacy of an intervention by presenting the initial specification of the techniques, goals, and format as well as specification of the theoretical approach. The manual content outline will be organized around:

1. Overview, description, and rationale including a description of the approach, background, and theoretical mechanisms of action.
2. Conception including etiological factors, factors associated with behavioral change, agent of change, case formulation, and assessment approach.
3. Treatment goals specification, evaluation, targeted behaviors, and negotiation of changes in goals
4. Contrast to other approaches with similarities and differences.
5. Specifications of defining interventions including recommended and proscribed elements.
6. Session content of unique and essential elements.
7. General format for delivery, session intensity, format, structure, and extra session tasks.

PHASE 2 –PILOT TESTING AND MANUAL REFINEMENT

Phase 2 will involve pilot testing the draft manual to examine content and feasibility with 3 groups of 10 female prisoners (n=30) in 3 participating centers (N=90 total sample), and will be subsequently modified by selected focus group members and project staff. Subjects for the pilot test will be randomly selected from in-prison treatment programs for the pilot, be consented for the study, and participate in up to 5 group sessions for the pilot intervention. The pilot is a pre-post test design. A research assistant will be present during the pilot sessions to work with the interventionist to note suggested changes to the pilot session, and provide feedback to the research team on intervention content. Since we are most interested in HIV risk behaviors, thinking errors, and relationships, we will measure the attitudes and intentions to practice safe sex and involvement in relationships before the intervention as well as thinking errors in a standard pre- and post-test design comparing the intervention group with a treatment as usual comparison group.

In addition, training manuals, and compliance measures will be developed by the manual development team during Phase 2. The overall approach to develop the manual will follow the procedures outlined by Carroll & Nuro (2002) which incorporates the following manual content: 1) Overview, 2) Discussion of issues, 3) Intervention goals and targeted behavior, 4) Discussion of other similar approaches, 5) Specifications for intervention session content, and 6) Format for the delivery and structure. The format for the delivery and structure of each session will follow the elements presented by Beck, Wright, Newman & Liese (1993): 1) Setting the agenda, 2) Mood check, 3) Bridge from the previous session, 4) Presenting the session, 5) Discussion and questions, 6) Summarizing, 7) Homework, and 8) Feedback.

Interventionist training and supervision

In addition to developmental focus group sessions during the initial project's two years to develop, modify and refine the therapy, interventionist training after interventionist selection will include training on the manual, ongoing therapy supervision as well as ongoing competency and adherence to the therapy by observation and audio taping. Initial training will include two-week training by project staff on the therapy approach and at least bi-weekly supervision during the pilot.

Interventionist Training: Two one-week training sessions are proposed in addition to ongoing supervision for quality control in order to assure consistent delivery of the therapy, which have been described by Carroll (2000). This training session will be carried out by the University of Kentucky. In preparation for the training sessions, we will ask the selected interventionists to read the manual as well as the overall project design contained in this application. Training will be carried out under the supervision of Dr. Lon Hays, Dr. Carl Leukefeld, and Dr. Cathy Martin. Dr. Hays, as University of Kentucky Department of Psychiatry clinical faculty, has extensive experience in treating patients. In addition, Dr. Martin and Dr. Leukefeld will provide training. Training content will include: Didactic presentations and case studies focused on the manual, interpretations of approaches, case presentations, role playing, analyzing cases, video taping practice sessions, and following the manual to understand therapeutic applications. This overall approach has been successfully used by the College of Medicine at the University of Kentucky as part of Robert Wood Johnson grant to revise our medical curriculum. The approach is also used by the Department of Psychiatry for other training activities.

This training will be coordinated and carried out by: (1) Lon Hayes M.D. who also has extensive experience with the provision of services for drug abusers which includes his position as Medical Director for the Center on Drug and Alcohol Research and Chair, Department of Psychiatry. (2) Carl Leukefeld who has had extensive experience in substance abuse teaching with physicians, physician assistants, and social workers at the University of Kentucky with a substance abuse practice course. (3) Cathy Martin, MD, who has extensive experience in drug abuse therapy with the University of Kentucky Department of Psychiatry in Lexington. Interventionists will also be rated on their compliance with the therapeutic approach using case studies that will be developed/adapted for training.

Interventionist Supervision: Supervising and monitoring the delivery and competency of the intervention will be carried out by Dr. Hays, Dr. Martin, and Dr. Leukefeld using the approach outlined by Carroll, (2000). Supervision will be provided weekly during the pilot. We will ask each interventionist to audio tape every group therapy session, and one tape will be randomly selected for weekly supervision. Individual sessions will be audio taped and reviewed for compliance to the manual. Since the intervention focuses on selected themes and their application to drug abusers' lives, supervision will focus on adherence to the specific "thinking error" targeted themes and will highlight adherence to the specific language of thinking errors. Written feedback will be provided to each interventionist for each session reviewed. In addition, specific notations will be made separately regarding problems and issues that could be modified/changed to make the intervention more consistent with the manual.

Interventionist Adherence Measures: The technology model used in psychotherapy research (Carroll & Rounsaville, 1990) will be used to guide the development and implementation of the delivery of intervention approaches to ensure that a “standard” dose of the intervention is provided during a set number of sessions. Critical to this approach is that the (1) intervention be specified in a manual, (2) interventionists be trained and clinically-supervised to deliver the intervention as uniformly as possible, and (3) intervention delivery be monitored for ensuring quality control. Delivery of a standard dose of the intervention is essential for making unambiguous conclusions about its efficacy and effectiveness. The proposed pilot will incorporate each of these approaches to ensure that a standard dose of the intervention delivered to each of the 30 clients in this study condition. (1) The CR-HIVF will be developed as a manual, with each session topic, background material, and assignment clearly specified for each of the individual and group sessions. (2) The principal investigator, study director, and one of the co-principal investigators will provide clinical training and supervision on for the study interventionists, emphasizing delivery of a “standard” dose of the intervention for each client. (3) The systematic monitoring of how well each interventionist adheres to the manual be accomplished using an approach adapted by Carroll et al. (2000) for assessing adherence to manual-guided therapies.

A structured set of questions will be used. Specific items for quantity ratings will include questions like “Did the interventionist address specific criminal thinking errors” and “To what degree did the interventionist address specific criminal thinking errors.” Specific items for quality ratings will include “Did the interventionist engage the clients’ interest in the materials” “To what extent did the interventionist re-direct the session specific criminal thinking errors” and “To what extent did the interventionist allow off-topic discussions.” This approach is similar to rating scales (Carroll, Nich, Sifry, Noro, Frankforter, Ball, Fenton & Rounsaville, 2000) used to assess interventionist adherence to behavioral interventions.

PHASE 3 – EVALUATION

Phase 3 will evaluate the intervention using a quasi-experimental two group design (N=120) across the 3 participating RC’s. Two groups of female prisoners in each RC (n=20 per group) will receive either the prison sessions with 3 community re-entry follow-up sessions by telephone or prison sessions without community re-entry sessions. Those who do not receive community follow-up sessions will receive a referral during the 3 month evaluation phase when the evaluation is completed.

Data collection will take place at baseline prior to randomization into the intervention groups, at post-intervention completion, and at 3-month post-release follow-up measures. The 3-month follow-up window is consistent with other studies which have measured behavior change intentions, self-efficacy, positive outcome expectancy, partner social norms, condom use, and ability to comfortably negotiate safer sex strategies (Belcher, et al., 1998; Schilling, El-Bassel, Hadden, & Gilbert, 1995; Grella, n.d.).

The two group design will compare participants who receive the prison sessions alone with participants who receive prison sessions combined with community re-entry sessions to

examine the development and feasibility of the intervention during the community re-entry transition. This design, although potentially limited with the sample size, will allow for comparisons in outcomes related to high risk sexual behaviors, drug use, thinking errors, and relationships across the two groups. Given the exploratory nature of this pilot study, the design is most appropriate because the group comparison will provide insight on the feasibility of implementing an HIV intervention during the transitional phase from prison to community in changing short-term outcomes, as well as helping to better understand the potential influence of criminal thinking and relationships in changing other outcomes. The key outcomes examined will be high risk sexual behaviors and drug use. Secondary outcomes to be examined will be recidivism, retention in the intervention sessions, changes in attitudes on relationships, changes in thinking errors and use of community treatment and other services.

Target population and sample: This 3-phase project will develop a manual driven intervention to improve treatment outcomes for female drug abusing prisoners at community re-entry. Incarcerated women, community women, prison treatment providers, community treatment providers, and community correctional supervisors (n=50) across 3 RC's (N=150) will be included in focus groups to develop the manual, and 120 women (40 women at each RC site) will be recruited to participate in the evaluation of the manualized intervention. The samples from each RC will be characteristic of the larger prison women's prison population receiving substance abuse treatment.

Evaluation instrumentation: The following instruments are proposed for the pilot evaluation. The following instruments have been selected after reviewing the literature to examine the primary outcomes of HIV risk behavior including sexual activity and drug use, and to examine the secondary outcomes of criminal thinking as related to relationships and support.

The following instruments will be used:

HIV Risk and Related Behaviors -- AIDS risk behaviors will be measured using the NIDA Risk Behavioral Assessment (RBA) and the Risk Behavior Follow-up Assessment (RBFA) questionnaires, which include questions related to drug use and sexual risks as well as partners and HIV protection. The RBA and RBFA were used in the NIDA funded Kentucky Cooperative Agreement study for which Leukefeld was PI. The RBA will be used to collect data on HIV/AIDS and related risk behaviors (NIDA, 1995).

Addiction Severity Index (ASI) – The ASI (McLellan et al. 1980) is a structured 40 minute interview to assess severity including drug use, employment, criminal behavior, psychological status, and physical health. ASI ratings have provided reliable and valid measures of problem severity for both drug and alcohol users and sensitive measures for treatment change (McLellan et al., 1980; McLellan et al., 1982; McLellan, et al., 1992).

Condom Self-Efficacy – This 28 item scale measures confidence about purchasing/using condoms and being able to negotiate the use of a condom with a new partner. Self-efficacy to condom use has been demonstrated to predict condom use (Kowalski et al, 1994) with a Cronbach's alpha of .91 and test-retest correlation of .81.

Readiness to Change Questionnaire -- This is a 12-item measure developed by Rollnick, Heather, Gold, and Hall (1992) to assess the early stages of change readiness. This measure is brief (12 items) and is used for persons who are unwilling to admit their behavior may be problematic. This measure allows for the classifying respondent into precontemplation, contemplation, preparation or action stages. Reliability and concurrent validity have been demonstrated, with the overall psychometrics ranging from moderate to very good.

Criminal Thinking Styles -- The Psychological Inventory of Criminal Thinking Styles Scale (Walters, 1995a; 1995b; 1996), an 80-item instrument, will assess criminal thinking in 8 areas. The scale shows good internal consistency, reliability, test-retest reliability, and predictive validity (Walters, 1996; Walters and Elliot, 1999).

Criminal Sentiments Scale – Modified (CSS-M) – The CSS-M is a 41 item self-report inventory that measures criminal attitudes, values, and beliefs which was developed by Simourd (1997). Specifically, the CSS-M will be used to measure criminal attitudes/thoughts related to criminal thinking, which are targeted by the intervention. The Chronbach’s alpha for the CSS-M is reported at .75 for a sample of criminals.

Credibility Scale (CS) -- The CS (Borkovec and Nau, 1972) will measure the credibility of the intervention.

Pride in Delinquency (PID). The Pride in Delinquency scale (Shields & Whitehall, 1991; Simourd & Van De Ven, 1999) is a 10-item inventory that measures the level of pride an individual has for engaging in criminal behaviors like “getting away from the police after a high speed chase” “selling cocaine” “striking someone who insults you.” It is frequently used with the CSS-M. Data from prisoners show good internal consistency reliability and predicts subsequent criminal behavior (Simourd, 1997, Simourd & Van De Ven, 1999).

Offender Neutralization. A scale developed by Shields and Whitehall (1991) will assess the extent to which the offenders cognitively minimize their criminal conduct, by blaming the victim, blaming the system, denial of responsibility, and denial of harm in their criminal activity. Analysis show good internal consistency reliability, good construct validity, and predicts subsequent criminal conduct (Shields and Whitehall, 1991).

Relationships: The role of relationships in decisions about sexual practices will be measured by the Sexual Relationship Power Scale (Pulerwitz, Gortmaker, & DeJong, 2000). The scale includes items to measure safer sex negotiation in relationships, the exertion of control in relationships, and decision making, and has been used to examine the association between relationship power and sexual practices. Analysis show solid internal reliability (0.85) and construct validity (Pulerwitz, Gortmaker, & DeJong, 2000).

Data Collection

Face-to-face interviews with participants will be used three times during the study to collect data (baseline, intervention completion, and 3-month follow-up) by an interviewer who

is skilled in establishing rapport with clients during the interview and in techniques for ensuring high-quality interview data. The baseline interview will be collected before randomization into the intervention and will include lifetime and recent measures of risky sexual behavior, drug use, criminal history, readiness to change, and criminal thinking attitudes (See the above instrumentation description). Key process variables also will be monitored by the interviewer, including client participation in the intervention and control sessions and treatment retention and/or early dropout. The interviewer will code whether or not each study participant attends the intervention sessions scheduled by regularly reviewing session attendance rosters for both groups.

For the intervention completion interview and 3-month follow-up interviews, specific sections of the baseline interview will be repeated in face-to-face interviews. The intervention post-test interview will focus on changes in attitudes on risky sex and risky drug use as well as criminal attitudes and thinking styles. Specifically, the post-test interview will include sections of the RBA, the Condom Self-Efficacy Scale, Criminal Sentiments Scale-Modified, Psychological Inventory of Criminal Thinking Styles, and the Pride in Delinquency Scale. Locator information will be collected. Participants will be reminded about the 3-month interview and the incentive, and an appointment will be scheduled for completing the 3-month follow-up interview. The 3-month follow-up interview will be structured to measure changes in HIV sexual risk behaviors, drug use, criminality, mood and affect, and criminal attitudes and thinking. Specifically, this interview will include the NIDA RBA, Condom Self Efficacy, Addiction Severity Index, Readiness to Change Questionnaire, Criminality Scale, Criminal Sentiments Scale-Modified, Psychological Inventory of Criminal Thinking Styles, Neutralization Scale, the Pride in Delinquency (PID) Scale, and the Credibility Scale.

Baseline data collection will begin before the intervention is initiated. Data collection will be carried out by the project interviewer who will travel to the prison facility. We will program the instruments into Computer Assisted Personnel Interview (CAPI) formatting using software C13 from Sawtooth. The Center is successfully using the CAPI in a three site study (Booth PI, RO1 DA15363 with Leukefeld as Co-PI) which is examining the natural history of rural stimulant use with the University of Arkansas and Wright State University. The CAPI interview will be installed on interviewers' laptop computers. Interviewers from the three sites will save their interview data on removable media (diskette, cd-rom, etc.) and send to the data manager at the lead center according to a specified schedule. The data manager will merge these batch files to the aggregate database, maintain the database, and perform data analyses following established CDAR data review and edit procedures.

Data Analysis and Data Management

The lead center will be responsible for both qualitative and quantitative data analyses.

Quantitative data from focus groups will be analyzed using Folio Views 4.2 Infobase. Folio Infobase will be used to identify categories and themes which will represent focus groups' input. Responses to each structured question will be entered directly into the Infobase using a structured short-answer format. Simultaneously, research codes for pre-determined and emergent categories will be developed and entered as index segments for specific "open coding" themes (Fielding & Raymond, 1998; Glaser, 1967; Strauss & Juliet, 1998). Open codes can be indexed and can be searched and specific topics consolidated. When open coding is completed, axial coding will be used as a second step to create categories and subcategories

which will be used to determine the number of intervention sessions and the content of the sessions (Strauss & Juliet, 1998).

Quantitative data will be analyzed using SPSS 12.0. SPSS will be used initially to generate descriptive reports which will focus on describing respondents on individual characteristics. The primary outcome variables are risky sexual behaviors (NIDA RBA) and risky drug use behaviors (NIDA RBA), with re-arrest (ASI) and criminal thinking (Walters, 1995) as secondary measures. The first set of planned analyses include: demographic characteristics, self-reports of the primary outcomes (HIV risk behaviors and drug use) and secondary outcomes (criminal thinking, relationships, and recidivism). Changes occurring between baseline and follow-up attitudes and opinions will be assessed in a repeated measures ANOVA framework with group assignment -- CR-HIVF in prison only or CR-HIVF in prison followed by community re-entry sessions -- as the between factors design and time (pre-test, post-test) as the within subjects design. A central analysis research question is to examine HIV attitudes and risk behaviors – including risky sex and drug use – with a focus on how these measures change differentially as a function of group membership after exposure to the intervention and how changes related to individual characteristics like criminality and criminal thinking.

In addition, the nonparametric McNemar test for comparing change in dichotomous variables will be used to examine changes between attitudes, opinions, and behaviors (which include questions about condom use, money for sex, etc.). For variables that are continuous (e.g., Readiness to Change) a repeated measures analysis of covariance (ANCOVA) approach will be used. Covariates will be entered as determined necessary to control for baseline differences. Most likely, pre-intervention criminal justice involvement, relationships histories, age, and race will be used as covariates. While the procedures outlined here will involve multiple tests, and thus may capitalize on chance, we believe the procedures to be appropriate for determining whether a larger trial is warranted. The central analysis questions for the pilot test will be to focus on the changes in attitudes, opinions, and behaviors that occur as a result of the intervention. Thus, the strategy is to examine changes in the period before and after the intervention using self reported and objective records compared to changes in the control group. Using Lipsey (1990) with an n of 60 in each group, a small effect size (.2), and an alpha=.05, power would be .10. Although the power is small, the purpose of this evaluation is to develop descriptive information and to demonstrate feasibility for continuing with a larger sample to provide additional power.

Stakeholder involvement

This project builds upon theory, clinical approaches, and research based interventions to develop the intervention in collaborative partnerships with corrections partners at three RC participating prisons for women and community treatment providers to develop the intervention. The project will specifically involve three women's prisons, prison treatment programs, prison treatment interventionists, community drug abuse treatment interventionists, and correctional supervisors to examine the feasibility, acceptability, and evaluate outcomes at community re-entry.

Project timeline

This three year project includes focus groups to develop a draft manual and pilot the draft manual during the first and part of the second year. The manual driven intervention will be refined; training and supervision procedures implemented, and compliance procedures selected in the second year of the project. The manualized intervention will be evaluated using a two-group quasi-experimental design during the project's third year.

Year One

- Convene 5 focus groups to identify content for the Female Thinking Errors and HIV (FTEH) intervention.
- Develop the initial 5 session manual.
- Pilot instrumentation, finalize instrumentation and enter data into CAPI.
- Pre-pilot and refine the manual with focus group feedback.

Year Two

- Develop intervention adherence measures
- Develop interventionists training protocols
- Train interventionists.
- Refine manual

Year Three

- Implement the intervention with 40 participants in 3 RCs (120 total).
- Collect baseline data
- Supervise intervention delivery.
- Collect post-intervention data.
- Descriptive data analysis.
- Collect 3-month follow-up data.
- Analyze and Report findings from baseline/follow-up data.

Proposed costs

A detailed budget is included as Appendix A for the lead center and participating centers. Costs are associated with developmental costs related to staffing, travel, training, supervision, data analysis, and participant incentives for the focus groups and data collection.

Human subjects

Every effort will be made in the protection of human participants and issues relating to subject confidentiality. In addition, this human participants protocol complies fully with the special protections pertaining to behavioral research involving prisoners as participants (Protection of Human Participants, Code of Federal Regulations, 45 CFR 46, Revised March 8, 1983). In this regard:

(a) None of the members of the University of Kentucky's Institutional Review Board (IRB) have any association with the Kentucky Department of Corrections. The University of

Kentucky has a member of its IRB with responsibility for reviewing criminal justice protocols (Section 46.304);

(b) All female prisoners who are incarcerated and returning to the community meeting eligibility requirements to participate in the research project will have an equal possibility of being selected. Selection for the project from those admitted to the groups will be random.

(c) Female prisoners who are incarcerated and returning to the community will be given the opportunity to participate in the research project; they will not be coerced in any manner to participate in the project, nor will there be coercion of any type after a subject has been selected for project participation; assurance exists that criminal justice officials will not take into account an individual's participation or non-participation in the project (Section 46.305), so participants can terminate their participation at any time without repercussions; and,

(d) This study, since it involves "research on social and psychological problems such as alcoholism and drug addiction," constitutes research permitted by NIH, PHS, and HHS involving prisoners as participants (Section 46.306).

Study Population/Sample

Female participants will be told about the nature and purpose/aims of the study, and the data collection. A member of the project research staff will also explain to each potential subject that:

- a) Neither participation nor refusal to participate in the research project will affect their legal status;
- b) No individual or identifiable data collected as part of the research project will be made available to criminal justice authorities; and
- c) If potential participants do NOT wish to participate, their normal parole date (if applicable) for termination will not be affected.

Potential respondents who choose NOT to participate in the research project will not be identified to their records, and as such, non-participation will NOT become a matter of official record in correctional files.

Subject Incentives

Participants will receive \$20 to participate in the focus groups and each of three data collections (baseline, post-test and 3-month follow-up data collections).

Confidentiality of Records

A Certificate of Confidentiality will be obtained from the National Institute on Drug Abuse which, under federal statute PL 94-255, prohibits all data collected during the course of the project from being used in any legal or criminal proceedings. Participants will receive a copy of the Certificate of Confidentiality. In addition, participants will be verbally informed and given a copy of the signed informed consent which describes the purpose of the study and the confidentiality safeguards.

All research data will be kept in locked file cabinets at the University of Kentucky Center on Drug and Alcohol Research. Each respondent will receive a unique identifying number. All research data collection instruments will be identified by this number only. The master list matching identifiers to specific participants will be maintained in a locked file at the

Center on Drug and Alcohol Research. Research data will be reported in aggregate form only. Hard copies of all data collection instruments will be destroyed at project completion. Computer files will be retained, but computerized identifying information will be destroyed when data collection and file building is completed. Participants will not be identified by name in analytic data files.

Potential Risks

The procedures to be used in this project involve conventional medical, psychological, and social science research methods that are routine in a study of this nature. The potential psychological risks will be discussed with participants during recruitment contacts to assist them in making an informed decision as to whether they wish to participate in the study. These potential psychological risks are primarily related to the possible psychological stress from discussing HIV/AIDS related high risk behaviors, drug use and criminality.

Potential Benefits

There could be significant potential benefits to society because the study will provide important information related to HIV/AIDS prevention. The proposed study may also provide information which can be used to improve HIV prevention interventions for female substance users involved in the criminal justice system who are leaving prison and transitioning to the community. In addition, the HIV/AIDS information and the intervention may have the potential for reducing the spread of HIV and other sexually transmitted diseases.

DATA SAFETY AND MONITORING PLAN

Data safety and quality is a priority for the University of Kentucky Center on Drug and Alcohol Research (CDAR). As the lead center, CDAR will ensure data safety and monitoring across participating research centers using written Data Safety and Monitoring Procedures (2001) have been developed by the University of Kentucky Center on Drug and Alcohol Research. It should be noted that each study protocol and all activities concerning human participants will be approved by the University of Kentucky IRB with the following requirements: (1) All participants must understand, agree to, and sign a consent form before participating. (2) Strict adherence to a participant's right to withdraw or refuse to answer questions is maintained. (3) The interview is completely confidential and no names will be associated with the interview. (4) CAPI data will be saved on the laptop in a secure data file in a lock box during transit. (5) At no time will a person who is not study staff be permitted to review identifying data (6) Consent forms and identifying information will be kept separate from the actual participant data. (7) All identifying information (consents, locator data, W-9s) will be kept locked at all times. (8) All documentation of IRB approval, original consents, Certificate of Confidentiality, human participants certification for staff, and other related study information will be filed and easily accessible to the PI and the Co-I serving as Study Director.

The established Data Safety and Monitoring Procedures (2001) include: (1) All staff, including data entry personnel and students, must successfully complete the Protecting Study Volunteers in Research Certification. (2) All staff must attend quarterly meetings and trainings on human participants. (3) Random audits for data safety are conducted twice each year. This audit will verify that all precautions are taken to secure data as specified by the IRB and to protect confidentiality of research participants. (4) Specific and clear protocols for adverse events and violations of study protocols are established. (5) Intensive data monitoring and quality control of every aspect of each study protocol will be conducted through extensive and ongoing reviews of interviews and locators, observation of recruitment, interviews, and screening participants. (6) Random participant verifications are completed to verify participant satisfaction, questions, and locator information. (7) Extensive data audits and verifications are completed. (8) Intensive data reports including recruitment and interview reports, contact and tracking reports, no show/refusal reports, and returned mail are prepared on a regular basis. Standardized reports record audit results.

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