

The National Institute on Drug Abuse Collaborative Cocaine Treatment Study

Rationale and Methods

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The National Institute on Drug Abuse Collaborative Cocaine Treatment Study is a large, multisite psychotherapy clinical trial for outpatients who meet the *DSM-IV* criteria for cocaine dependence. For 480 randomized patients, the outcomes of 4 treatments are compared for an 18-month period. All treatments include group drug counseling. One treatment also adds cognitive therapy, one adds supportive-expressive psychodynamic therapy, and one adds individual drug counseling; one consists of group drug counseling alone. In addition, 2 specific interaction hypotheses, one involving psychiatric severity and the other involving degree of antisocial personality characteristics, are being tested. This article describes the main aims of the project, the background and rationale for the study design, the rationale for the choice of treatments and patient population, and a brief description of the research plan.

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The National Institute on Drug Abuse (NIDA) Collaborative Cocaine Treatment Study is a multisite clinical trial investigating the efficacy of 4 treatments for outpatients with cocaine dependence. To our knowledge, it represents the largest clinical trial conducted to date on psychotherapy and counseling for cocaine dependence. This article describes the rationale for the study design, which was developed in response to 2 NIDA Requests for Application for a Cooperative Agreement research program.^{1,2} The first phase of the project (conducted from October 1991 to July 1993) involved site selection, protocol development, and staff recruitment. The second phase (conducted from July 1993 to July 1994) involved training the staff to an acceptable level of competence,

field testing the assessment procedures and protocol treatments, and obtaining preliminary pilot data relevant to the hypotheses of the study. The main clinical

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trial began in July 1994, and data collection is scheduled to end in January 1998. This article describes the main aims of the study, the background for the project, and a description of the main elements of the study design.

AIMS OF THE NIDA COLLABORATIVE COCAINE TREATMENT STUDY

This study investigates the relative efficacy of 4 manual-guided treatments for outpatients who meet the *DSM-IV* criteria for cocaine dependence: (1) group drug counseling (GDC) alone, (2) individual cognitive therapy (CT) plus GDC, (3) individual supportive-expressive (SE) psychodynamic therapy plus GDC, and (4) individual drug counseling (IDC) plus GDC. The following main effects and interaction hypotheses are being tested.

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Main Effects

One of the primary aims of this study is to compare the short- and long-term efficacy and patient acceptance of CT plus GDC, SE psychodynamic therapy plus GDC, IDC plus GDC, and GDC alone. The comparison of the combined individual and group treatments with GDC alone addresses the practical question of whether it is sufficient to treat cocaine-dependent patients with GDC alone. The IDC plus GDC treatment also addresses a practical question: if GDC needs to be supplemented with individual treatment, is a professional psychotherapist needed or are the services of a substance abuse counselor equally effective? The IDC plus GDC treatment is also included to control for the extra time with an individual counselor that those patients in CT and SE psychodynamic therapy will receive.

Interaction Hypotheses

There are 2 hypotheses: (1) Patients with higher levels of psychiatric severity (concurrent psychiatric symptoms) will show a better response to the psychotherapies (CT plus GDC and SE psychodynamic therapy plus GDC) compared with the drug counseling treatments (IDC plus GDC and GDC alone). (2) Patients with more antisocial personality characteristics will have a better response to CT plus GDC compared with SE psychodynamic therapy plus GDC, but patients without antisocial personality characteristics will have a better response

to SE psychodynamic therapy plus GDC compared with CT plus GDC.

BACKGROUND

Developing and testing treatments for cocaine use disorders is a high national priority. The *National Institute on Drug Abuse Household Survey 1994*³ indicates that the prevalence of frequent cocaine use has remained at 0.3% of the population since 1985. The effects of cocaine extend beyond the individual user and are wide ranging, especially in the areas of drug-related violence and risk behaviors associated with the human immunodeficiency virus. The development of successful treatments for cocaine use disorders, therefore, has the potential for a notable effect on the health of cocaine users; the larger social and medical problems associated with its use could also be affected. Given the magnitude of the problem, the NIDA determined that a controlled clinical trial of the most promising psychotherapy and counseling approaches for cocaine dependence was warranted. Selection of the treatments for study was based on practical considerations (eg, clinical relevance) and prior empirical work, particularly the studies by Woody et al^{4,5} on psychotherapy and counseling approaches for opiate dependence. The treatments chosen for this study included IDC and GDC, SE psychodynamic therapy, and CT.

Some form of IDC or GDC by a nondoctoral-level provider is the standard treatment offered to substance abusers in most clinical settings.⁶ Psychodynamically ori-

ented psychotherapy continues to be the most widely used professional treatment.⁷ In preparation for this project, NIDA staff conducted an informal survey of clinicians who work with substance abusers. This survey suggested that psychodynamic therapy was also frequently used in the community for the treatment of these patients. Cognitive-behavioral therapies are also used commonly in the community, with cognitive-behavioral relapse prevention strategies increasingly incorporated into the treatment of substance abusers in particular.⁸ Cognitive-behavioral and psychodynamic therapies not only represent 2 approaches that are commonly used but also serve as contrasting theoretical perspectives because of their distinctiveness from each other.

It is not at all clear if these treatments are efficacious for cocaine dependence. In recent years, the results of several controlled trials testing these treatments, alone or in combination with psychopharmacological treatments for cocaine dependence, have been published; this literature has been reviewed elsewhere.^{9,10} Several studies have supported the efficacy of cognitive-behavioral relapse prevention treatment for cocaine use disorders,^{11,12} particularly for delayed effects emerging at follow-up.¹³ Promising results using a behavioral therapy (contingency contracting and community reinforcement) have also been reported.¹⁴ Less promising evidence concerning the use of interpersonal psychotherapy or psychodynamic therapy has been reported.^{15,16}

The Role of Psychiatric Severity

Rather than focus solely on main effect comparisons between treatments in clinical trials, several researchers have suggested that it is more relevant to clinical practice to examine interaction effects, with an eye toward matching different treatment modalities to patient characteristics.¹⁷⁻¹⁹ One known modifier of response to psychotherapy is level of psychiatric severity.²⁰ Substance-dependent patients with notable psychiatric symptoms may need a treatment that addresses these ongoing psychiatric problems that might be fueling the addictive process or making the substance use disorder more difficult to treat. In contrast, substance-abusing patients with low levels of psychiatric symptomatology might find more intensive psychotherapeutic treatments to be less relevant. For them, standard drug counseling may suffice.

The available literature tends to support these views. In an examination of outcomes in 6 rehabilitation programs, McLellan et al²¹ found that patients with low levels of psychiatric severity improved in all treatment programs, whereas patients with high levels of psychiatric severity showed virtually no improvement. Rounsaville et al²² found that higher psychiatric severity was associated with poorer outcome in current functioning and psychosocial adjustment but not substance use outcome in a 2.5-year follow-up of persons addicted to opiates. Most relevant to this study, Woody et al²³ found that opiate-dependent patients with a high psychiatric severity achieved better psychiatric and drug use outcomes when they received psychotherapy in addition to IDC than when they received only the latter. With the use of an alcohol-dependent sample, Kadden et al²⁴ and Cooney et al²⁵ found that patients with a higher psychiatric severity did bet-

ter in coping skills training group therapy than in interactional group therapy, but both treatments were equally effective for patients with low psychiatric severity.

The previously described studies indicate consistently that patients with higher levels of psychiatric severity show greater improvement when their treatment includes professional psychotherapy. However, the benefits of this interactional model of treatment matching have not been studied prospectively in a cohort of cocaine-dependent patients.

The Role of Antisocial Personality Disorder

Beutler¹⁸ reported that, in 8 of 9 studies, patients low on a trait measure of antisocial personality disorder did better in verbal psychotherapy compared with behavioral therapy. Several more recent studies found that patients with higher levels of traits associated with antisocial personality disorder fared better in more directive treatments.²⁴⁻²⁷

The likelihood that only a few cocaine abusers are likely to manifest few traits associated with antisocial personality disorder might explain the poor results from interpersonal and psychodynamic treatments in controlled studies. These findings serve as the basis for the hypothesis of the current project: patients who are more impulsive and who have more characteristics of antisocial personality disorder will have better outcomes in cognitive-behavioral therapy, whereas less impulsive patients will have better outcomes in psychodynamic therapy.

RESEARCH PLAN

Patient Selection

The selection criteria were designed to identify a representative group of primary cocaine-dependent patients who would be suitable for outpatient treatment and whose personal characteristics and life circumstances would not interfere with study participation. Patients aged 18 to 60 years are included if they have a principal current diagnosis of cocaine dependence or cocaine dependence in early partial remission (as determined by DSM-IV criteria). The principal diagnosis is established using a 0 to 8 severity rating scale adapted from the *Anxiety Disorders Interview Schedule-Revised*²⁸ that reflects the diagnostician's evaluation of the subjective distress and functional impairment associated with the diagnosis. In addition, patients must have used cocaine at least once in the 30 days before enrollment, have a current postal address and plan to live in the area for the next 2 years, be able to provide the name of at least 1 person who can generally locate their whereabouts, and be able to understand and complete the assessment measures. Explicit written, informed consent was obtained from all patients.

Patients are excluded if (1) they have a principal diagnosis of alcohol or polysubstance abuse or dependence; (2) they have a diagnosis of current opioid dependence or opioid dependence in early partial remission (sustained full remission is acceptable); (3) there is evidence of dementia or another irreversible organic brain syndrome; (4) they have a psychotic disorder; (5) they have any history of or current bipolar disorder; (6) they are at current imminent suicide or homicide risk, require hospitalization or resi-

dential treatment, or are in a halfway house; (7) they are unwilling to discontinue a current psychotherapeutic treatment; (8) they must continue to receive a psychotropic medication; (9) they have any life-threatening or unstable medical illness or a medical illness that can create marked change in mental state; (10) incarceration is impending; (11) they were hospitalized more than 10 days of the past 30 days for treatment of cocaine use; (12) they are currently legally mandated for treatment; or (13) they are more than 12 weeks pregnant.

Therapist and Drug Counselor Selection and Training

For the chosen treatments to have the best chance possible of demonstrating efficacy, they must be provided under optimal conditions (ie, by therapists and drug counselors with specialized expertise and training). Details of therapist and counselor selection and training will be reported in separate articles. Briefly, all therapists and counselors were first selected from a pool of applicants. Training then consisted of 4 weekend workshops plus supervised experience with 4 patients per therapist or counselor. Ratings of adherence and competence of treatment sessions by supervisors and independent raters were used to make final decisions about certifying each therapist or counselor as performing the treatment adequately enough to participate in the main trial.

Patient Screening and Randomization Procedures

Patients are initially screened for study participation via telephone or on a walk-in basis to determine if the basic inclusion criteria are met. If the criteria are met, patients return for an enrollment evaluation, which includes a urine drug screen. To be randomized, patients must complete the enrollment evaluation, still meet the inclusion criteria, and complete an orientation phase that includes attendance and assessment requirements. The patient is required to attend 3 visits at the clinic within 14 days, including 1 group session at which another urine drug screen is collected, and 2 case management visits. Group counselors suggest attendance at local self-help groups, such as Cocaine or Alcoholics Anonymous; promote human immunodeficiency virus risk reduction; and address housing, job, or financial needs. This orientation phase selects for treatment only those patients with enough motivation to attend at least a few sessions. Although it might ideally be of interest to test treatments on the full range of patients who contact a treatment program, it seems likely that psychotherapy treatments only have a chance of efficacy with patients sufficiently motivated to attend a minimal number of orientation sessions.

After satisfactory completion of the postorientation assessments, patients are randomized to treatment. Random assignment to treatment uses a special technique known as adaptive or "urn" randomization.²⁹ Urn randomization ensures equivalence of the groups on preselected variables that may relate to outcome across treatments or that may interact with type of treatment to affect outcome.

For this project, the following factors were included in the adaptive randomization algorithm: sex, marital status, employment status, mode of cocaine use, psy-

chiatric severity, and degree of antisocial personality characteristics. Sex, marital status, employment status, and mode of cocaine use were chosen because these variables have been associated with outcome, retention, or both in prior studies^{6,30} or within our pilot data. Psychiatric severity and degree of antisocial personality disorder were chosen because they were specifically hypothesized to interact with treatment modality in relation to outcome. The urn randomization was separate for each site to ensure that treatments were balanced on the relevant factors within each site.

Treatments

Format. All 3 individual treatments have a 6-month active phase and a 3-month booster phase. The same session schedule is followed in all 3 individual treatments. During the first 3 months, individual sessions are held twice per week; during the next 3 months, sessions are held weekly. During the booster phase, 1 session is held each month. For the GDC modality, group sessions are held once a week for the 6 months of the active phase. During the booster phase, patients in the GDC alone treatment group meet individually with the group counselor once per month for a half hour visit.

Cognitive Therapy. Cognitive therapy provided in this study follows a detailed manual.³¹ This treatment is based on the assumption that substance use disorders are related to individuals' maladaptive beliefs and related thought processes. Cognitive therapy for substance abuse consists of 5 components: (1) collaboration, (2) case conceptualization, (3) structure, (4) socialization to the cognitive model, and (5) use of cognitive and behavioral techniques. Among the techniques used are Socratic questioning, advantages-disadvantages analysis, monitoring of drug-related beliefs, activity monitoring and scheduling, behavioral experiments, and role playing.

SE Psychodynamic Therapy. Brief SE psychodynamic therapy as conducted in this study follows the general SE psychodynamic therapy treatment manual³² and a more specific variant of it developed for cocaine abusers.³³ According to this model, the problems associated with the use of cocaine and with its cessation are viewed in the context of an understanding of the person's interpersonal and intrapsychic functioning. The core conflictual relationship theme³⁴ concept provides the framework for this understanding. The patient's core conflictual relationship theme, defenses, and views of self influence complicate the steps needed to stop using cocaine and to address the problems involved with cocaine dependence. The therapist uses supportive and interpretive techniques, particularly interpretations related to aspects of patients' core conflictual relationship themes, that most interfere with the achievement of patients' goals.

Individual Drug Counseling. This modality³⁵ is based on a widely used approach to the treatment of drug addiction. It is time limited and focuses primarily on helping the patient achieve and maintain abstinence by encouraging behavioral changes, such as avoiding drug triggers, structuring one's life, and engaging in healthy behaviors (eg, ex-

ercise). Individual drug counseling is a staged approach with specific interventions keyed to the stages. In content and structure, it is consistent with the philosophy of the 12-step approach, specifically that addiction is a disease that damages the person physically, emotionally, and spiritually and that recovery is a gradual process. Participation in self-help groups is strongly encouraged.

Group Drug Counseling. This treatment³⁶ is designed to educate patients about the important concepts in addiction recovery, to strongly encourage participation in 12-step programs, and to provide a supportive group atmosphere in which members can express feelings, discuss problems, and learn to draw strength from one another. The group is progressive; the first 3-month phase is psychoeducational, and the second 3-month phase consists of open discussion with a focus on patients' helping each other solve problems in recovery.

Assessments

The assessment battery was designed to capture multiple domains: diagnoses, substance use patterns, psychopathological features or symptoms, quality of life, treatment services use, theory-specific measures of mediators of outcome, treatment process, attrition, and motivation for treatment. Most assessments are made at enrollment (or immediately following the orientation phase) and at monthly intervals during the active (months 1-6) and follow-up (months 9, 12, 15, and 18) phases. In addition, patients receive an assessment when they drop out of treatment or violate protocol.

The primary outcome measure is the Drug Use Composite Scale of the Addiction Severity Index, a measure commonly used in substance abuse treatment with available reliability and validity data.³⁷⁻⁴⁰ This measure will be used to assess relative reduction in drug use during the active and follow-up phases of the protocol. Observed urine samples, collected once a week at group sessions, will be used as a secondary outcome measure. Urine samples will be used to assess time until remission (ie, 4 weeks of no drug use).

In addition to the main efficacy measures, a primary dependent variable of interest is retention in treatment. Days until a patient drops out of treatment or otherwise violates the protocol will be used as the measure of retention.

Psychiatric severity is assessed via the psychiatric severity composite score on the Addiction Severity Index. The degree of antisocial personality characteristics is assessed using the Socialization Scale of the California Psychological Inventory. These measures have been used successfully in previous research on psychiatric severity^{21,23} and antisocial personality traits,^{24,25} respectively.

Power Analysis and Sample Size Determination

There is no single power calculation for a large, complex study like this one. Power will vary as a function of distribution of outcome measure, main effects vs interactional effects, and expected effect size. For the Addiction Severity Index, as the outcome measure analyzed via

an analysis of covariance, the power to detect main effects is high (0.90-0.96) assuming 120 patients (30 per site) randomized into each of 4 treatments, 33% attrition (ie, lack of data), a type I error of 0.05, and effect sizes of 0.30 to 0.50 for our contrasts of interest.

Analyzing each interaction separately (SE psychodynamic therapy vs CT at 2 levels of antisocial personality characteristics and SE psychodynamic therapy plus CT [pooled] vs IDC at 2 levels of psychiatric severity), we computed the size of the interaction effect that can be detected with a power of 0.80 and a Bonferroni-corrected type I error of 0.025. As previously described, the sample size is 120 per arm of the study and there is 33% attrition. We found a Cohen $F=0.55$ for degree of antisocial personality characteristics and $F=0.48$ for the psychiatric severity interaction. Thus, with our proposed sample size, and correcting for attrition, the Bonferroni-corrected interaction tests are sensitive to moderate-sized effects.

The statistical power for detecting differences in our other main outcome of interest, retention rates, was also examined. With the use of retention rates (in which dropout is defined as no contact with a patient for 4 consecutive weeks) from our training phase of 90% at 1 month, 70% at 3 months, and 50% at 6 months and a power of 80%, an exponential function predicting dropout at time t months was calculated and used for power analysis for survival data. With the use of the method of Zelen and Dannemiller,⁴¹ the study's sample size was found to be adequate to detect a moderately small hazard ratio of 1.8 for each Bonferroni-corrected (2-tailed) pairwise comparison of the 4 treatments, with a power of 0.80.

Data Analysis

The initial analysis of the main treatment data will consist of analyses of the patterns of retention. This will be performed in a time-to-event analysis using the definition of retention previously given. Analyses of differences in efficacy using the Addiction Severity Index drug use composite score will be done via longitudinal regression approaches that allow for the use of all data collected. Additional cross-sectional analyses (analysis of covariance on 3- and 6-month outcomes) will be performed, as well as time-to-event analysis using the measure of days until abstinent determined from the urine data. Type of treatment, site, psychiatric severity, and degree of antisocial personality disorder will be the main independent variables for all of the previously described analyses. Statistically significant omnibus tests will be followed by post hoc comparisons of individual treatment modalities, as appropriate.

Several samples will be analyzed. An intent-to-treat pragmatic analysis that uses all data collected on patients, regardless of whether the patient was a dropout or a protocol violator, will be conducted.⁴² Further analyses using only data available on patients up to dropout, protocol violation, or therapy completion will also be conducted. In this latter analysis, an attempt is made to discern the effects of the therapies themselves, free of the effects of other treatments that patients may have received after dropping out of the program or otherwise violating protocol.

Various secondary analyses examining other outcome measures, mediators of outcome, and predictors of outcome will also be performed. The details of these analyses will be discussed in subsequent reports.

SIGNIFICANCE

To our knowledge, this study is the largest, most well-controlled study of manual-guided psychotherapy and counseling for cocaine dependence yet conducted. The study is likely to yield practical information about the treatment of these patients, such as answers to these basic questions: Is professional psychotherapy a useful addition to the standard drug-focused group counseling? Are there patient characteristics (eg, psychiatric severity or degree of antisocial personality characteristics) that interact with type of treatment, thereby providing guidance to clinicians for making better matches between patients and treatments? The multisite nature of this project will allow for the examination of the extent to which answers to these questions are robust across different sites.

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