

# Psychosocial Treatments for Cocaine Dependence

## National Institute on Drug Abuse Collaborative Cocaine Treatment Study

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**Background:** This was a multicenter investigation examining the efficacy of 4 psychosocial treatments for cocaine-dependent patients.

**Methods:** Four hundred eighty-seven patients were randomly assigned to 1 of 4 manual-guided treatments: individual drug counseling plus group drug counseling (GDC), cognitive therapy plus GDC, supportive-expressive therapy plus GDC, or GDC alone. Treatment was intensive, including 36 possible individual sessions and 24 group sessions for 6 months. Patients were assessed monthly during active treatment and at 9 and 12 months after baseline. Primary outcome measures were the Addiction Severity Index–Drug Use Composite score and the number of days of cocaine use in the past month.

**Results:** Compared with the 2 psychotherapies and with GDC alone, individual drug counseling plus

GDC showed the greatest improvement on the Addiction Severity Index–Drug Use Composite score. Individual group counseling plus GDC was also superior to the 2 psychotherapies on the number of days of cocaine use in the past month. Hypotheses regarding the superiority of psychotherapy to GDC for patients with greater psychiatric severity and the superiority of cognitive therapy plus GDC compared with supportive-expressive therapy plus GDC for patients with antisocial personality traits or external coping style were not confirmed.

**Conclusion:** Compared with professional psychotherapy, a manual-guided combination of intensive individual drug counseling and GDC has promise for the treatment of cocaine dependence.

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**I**N 1990, THE National Institute on Drug Abuse concluded that a public health priority was to determine the efficacy of psychosocial therapies for cocaine dependence. Literature<sup>1,2</sup> on the treatment of methadone-maintained opiate-dependent patients suggested that professional

### See also pages 503 and 505

psychotherapy was a useful addition to standard drug counseling approaches, especially for patients with high levels of concurrent psychiatric symptoms (ie, psychiatric severity). Matching patients to treatments based on the level of psychiatric severity was suggested by other studies of patients with mixed-substance-use disorders<sup>3</sup> or alcohol dependence,<sup>4</sup> as was matching based on the presence of antisocial personality traits (or an externalizing vs internalizing coping style).<sup>4,5</sup> The National Institute on Drug Abuse issued Requests for Applications (Cooperative

Agreement Research Program DA-91-04: “Maximizing the Efficacy of Psychotherapy and Drug Abuse Counseling Strategies in the Treatment of Cocaine Abusers”; January 1990 and February 1991) to conduct a randomized, multisite clinical trial to evaluate the efficacy of psychosocial therapies for cocaine dependence, with an interest in both comparing the main effects of the treatments and specific hypotheses on patient-treatment interactions. Detailed information on the project has been published.<sup>6</sup> We report the main study results, including data from the active phase of treatment (months 1-6) and 9- and 12-month outcomes.

The study design contrasted 4 treatments. In 2 of these, professional psychotherapy, either cognitive therapy (CT)<sup>7</sup> or

A complete list of the members of the National Institute on Drug Abuse Collaborative Cocaine Treatment Study and the affiliations of the authors appears at the end of this article.

This article is also available on our Web site: [www.ama-assn.org/psych](http://www.ama-assn.org/psych).

## PATIENTS AND METHODS

The research methods<sup>6</sup> and therapist training<sup>12</sup> have been presented elsewhere and will be briefly described here. A total of 487 patients were randomly assigned to treatment at 5 sites: the University of Pittsburgh (Western Psychiatric Institute and Clinic), Pittsburgh, Pa; the University of Pennsylvania Medical School, Philadelphia; Brookside Hospital, Nashua, NH; Massachusetts General Hospital, Boston; and McLean Hospital, Belmont, Mass (**Table 1**).

### PATIENTS

Patients were recruited from the following sources: 45.6% by newspaper or flyer, 21.9% from substance abuse treatment centers, 18.4% referred by a friend or an acquaintance, 7.6% from mental health centers, and 6.5% from private mental health providers. The inclusion criteria were a principal diagnosis of *DSM-IV*<sup>13</sup> cocaine dependence (current or in early partial remission), aged 18 to 60 years, and cocaine use in the past 30 days. The principal diagnosis was established using a severity rating scale of 0 to 8 adapted from the *Anxiety Disorders Interview Schedule-Revised*<sup>14</sup> that reflects the diagnostician's evaluation of subjective distress or functional impairment. Subjects were excluded from the study at a screening or intake interview for the following reasons (percentage of those excluded for each reason given in parentheses; many were excluded for more than 1 reason): does not meet criterion of cocaine dependence (43.6%); cocaine not primary drug (11.7%); person's age is not between 18 and 60 years (2.6%); has not used cocaine more than 1 day in past month (22.1%); does not have stable living situation (6.7%); is unable to understand forms or give consent (8.3%); the principal diagnosis is alcohol dependence (22.6%), opioid dependence (current or in early partial remission) (14.0%), or polysubstance dependence (16.4%); has dementia or other irreversible organic brain syndrome (8.8%), psychotic symptoms (14.0%), history of bipolar I disorder (18.1%), and/or a risk of imminent suicide or homicide (15.2%); is unwilling to discontinue current psychotherapeutic treatment (29.8%); needs to continue taking a psychotropic medication (29.8%); has a life-threatening or unstable medical illness (8.8%); is awaiting incarceration (14.3%); has been hospitalized for the treatment of substance abuse for more than 10 of the past 30 days (7.9%); has a mandate for treatment by legal or children protective services (17.9%); resides in a halfway house (4.5%); is more than 12 weeks' pregnant (4.5%); is not interested in participating in a study (16.0%); will not be in the area for 1 year (5.0%); and cannot meet the demands of the study (group or sessions per week) (20.7%).

Subjects were usually screened by telephone and, if appropriate, invited for an intake visit. Following the intake visit and informed consent, the patients began an orientation phase that included both attendance and assessment requirements designed to select those with enough motivation to attend at least a few sessions. The patient was required to attend 3 clinic visits within 14 days, including 1 group session and 2 case-management visits, before being randomly assigned to treatment. In the orientation phase, group counselors suggested attendance at self-help groups such as Cocaine or Alcoholics Anonymous; promoted

human immunodeficiency virus risk reduction; and addressed housing, job, or financial needs. Patients meeting attendance requirements then had a postorientation assessment of 1 to 2 days.

A total of 2197 persons were screened by telephone, of whom 1777 (80.9%) met basic inclusion criteria and were invited for an intake visit, and 420 were ineligible for the study. Of 1777 eligible persons, 937 (52.7%) attended an intake visit, and most (870 persons) began orientation by attending another visit after the first intake session. Of the 937 persons who came to the first intake visit, 13 met exclusion criteria and 54 did not return. Of the 870 persons who started the orientation phase, 254 (29.2%) did not complete the attendance requirements, and 129 (14.8%) did not complete the assessment requirements, leaving a final sample of 487.

After the orientation phase (before randomization), only 3 persons were ruled out by structured diagnostic assessment: 2 persons for opioid dependence and 1 person for a psychotic disorder not otherwise specified. Overall drug use, severity of cocaine use, psychiatric severity, and antisocial personality traits were not significantly associated with attrition from intake to randomization.

### RANDOMIZATION PROCEDURE

Following a satisfactory completion of postorientation assessments, patients were centrally randomly assigned to treatment from the coordinating center, separately at each site using a computerized "urn" randomization procedure,<sup>15</sup> with sex, marital status, employment status, mode of cocaine use, psychiatric severity, and antisocial personality traits score used to balance the treatment conditions on these potential prognostic factors.

### THERAPISTS

As described elsewhere,<sup>12</sup> extensive attention was paid to the selection, training, and competence of therapists and counselors in the initial training phase. For the main trial, 15 CT therapists, 13 SE therapists, 12 individual drug counselors, and 10 group drug counselors participated. Different therapists or counselors worked at each site. Although SE, CT, and IDC therapists or counselors were similar in age and sex, individual drug counselors had substantially more experience treating substance abuse or dependent patients than did SE and CT therapists (**Table 2**). Individual drug counseling had a greater proportion of minority and female counselors than SE and CT.

### TREATMENTS

Treatment consisted of a 6-month active phase and a 3-month booster phase. Individual treatment sessions (50 minutes) were held twice per week during the first 12 weeks, weekly during weeks 13 to 24, and monthly during the booster phase. Group drug counseling sessions (1½ hours) were held weekly for the 6 months of the active phase. Patients in GDC alone met with the group counselor individually monthly for a half hour during the booster phase. Treatment was free of charge.

The treatment approaches have been described elsewhere.<sup>12</sup> Cognitive therapy followed a detailed manual<sup>7</sup> for CT of substance abuse or dependence. Brief SE

psychodynamic therapy followed the general SE treatment manual by Luborsky,<sup>16</sup> with modifications<sup>8</sup> for cocaine dependence. Individual drug counseling followed a manual<sup>11</sup> with specific stages, tasks, and goals based on the 12-step philosophy. Group drug counseling followed a manual<sup>10</sup> designed to educate patients about the stages of recovery from addiction, to strongly encourage participation in 12-step programs, and to provide a supportive group atmosphere for initiating abstinence and an alternative lifestyle.

## ASSESSMENTS

### Overview

Assessments were completed at intake, at the end of orientation, monthly during the active phase of treatment, and at months 9, 12, 15, and 18 after randomization. Although the assessment battery covered multiple domains, in this article we focus on the main drug use outcomes. Patients were paid a nominal fee for participating in postintake research assessments.

### Instruments

The primary outcome measure was the Drug Use Composite score from the interview-based Addiction Severity Index (ASI).<sup>17</sup> One specific item from the drug use scale, the number of days using cocaine in the past 30 days, was also examined. The ASI interviewers were blind to the treatment condition. Cocaine use was also assessed by weekly self-reports<sup>18</sup> and weekly observed urine specimens, which were sent to a central laboratory and assayed for cocaine and other drugs.

Based on the work of Kadden et al,<sup>4</sup> our interaction hypothesis about antisocial personality traits or external coping style was examined using the Socialization scale of the California Psychological Inventory (CPI),<sup>19</sup> administered at intake. To test the hypothesis concerning the degree of psychiatric symptoms interacting with the treatment condition, a composite measure of 4 scales—the Hamilton Rating Scale for Depression,<sup>20</sup> the Beck Anxiety Inventory,<sup>21</sup> the Brief Symptom Inventory,<sup>22</sup> and the ASI–Psychiatric Severity Composite score—was created by converting each scale to a standard score and then averaging the scores.

The diagnosis of substance use disorders and other Axis I disorders was made at intake by a Structured Interview for Axis I and II for the *DSM-IV*<sup>23</sup> by trained clinicians, and the Hamilton scale and ASI were administered by trained research assistants.

Measures of both patient and therapist perspectives on the quality of the therapeutic alliance—the Helping Alliance Questionnaire<sup>24</sup> and the California Psychotherapy Alliance Scale<sup>25</sup>—were obtained at sessions 2 and 5.

### Protocol Violation

Protocol violation was used as an index of attrition. All patients who violated the protocol, however, continued to receive monthly assessments and could return to treatment. Patients were considered to have violated the protocol if they met any of the following conditions: had no face-to-face contact with their individual therapist or group counselor

(GDC condition) for 30 consecutive days (also labeled “dropouts”), were hospitalized for psychiatric or substance abuse disorder for more than 7 days, had medical hospital admission or jail stay for more than 30 days, or sought or needed additional or alternative treatments (eg, inpatient treatment) or psychotropic medication. A protocol violations committee reviewed all cases using standardized criteria to decide if a patient’s clinical situation warranted protocol violation status.

### Completeness of Data

Of the 8 monthly assessments (months 1–6, 9, and 12), patients completed a mean of 6.1 assessments, with no significant differences between treatment conditions (Cochran-Mantel-Haenszel test,  $\chi^2_3 = 1.33$ ;  $P = .72$ ). At least 1 of the 6 active-phase postintake ASI monthly assessments was obtained from 94.3% of the 487 patients; 85.2% of patients completed a month 5 or month 6 assessment, and 83.2% completed either the 9- or 12-month follow-up assessment.

Of all potential weekly urine specimens, 42.6% were collected, assuming a potential of 24 specimens per patient if a patient attended all sessions offered. Because of missing urine data, the urine data were used 2 ways: to examine the validity of self-reported drug use measures and as part of a composite cocaine use measure.

### Concordance of Assessments of Cocaine Use

The correlation between the percentage of cocaine-free urine specimens during the first 4 weeks of treatment and the report of cocaine use in the past 30 days from the ASI was 0.64 ( $P < .001$ ). We also compared the weekly self-report of cocaine use with urine test results during the first month of treatment, coding the month as “not abstinent” if any cocaine was used. The  $\kappa$  coefficient for this comparison was 0.64. Sensitivity (conditional agreement given a drug-negative urine test result) was 0.74, and specificity (conditional agreement given a drug-positive urine test result) was 0.90. Thus, 10% of the urine test results indicated some use when the patient denied use.

### Composite Cocaine Use Measure

A composite outcome measure of cocaine use was constructed by pooling information from multiple measures (urine drug tests, ASIs, and weekly cocaine use inventory) to code each month of treatment as abstinent vs not abstinent. Any indication of cocaine use from the 3 measures would lead to a “not abstinent” month. If no information was available for a given month (which occurred 19% of the time), the month was coded as “not abstinent.”

### Treatment Integrity

Assessments of treatment fidelity and discrimination were obtained during the training phase and the main trial using independent audiotape ratings. Training phase data indicated that the treatments were implemented as intended and that the treatment conditions could be readily discriminated.<sup>26,27</sup>

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## STATISTICAL ANALYSIS

Preliminary to efficacy analyses, the distributions of the variables were examined and revealed nonnormal distributions on several variables. Days using cocaine within the past 30 days and the ASI-Psychiatric Severity Composite score had highly skewed distributions; therefore, a shifted log transformation was performed on each.

Because our pilot or training phase data and main trial data indicated that almost all of the average patient improvement was evident by the first month, we implemented a general mixed-model analysis of variance approach (using PROC MIXED in the Statistical Analysis System, version 6; SAS Institute, Inc, Cary, NC) that examined mean drug use during monthly assessments (compared with baseline), rather than assuming a linear slope during time. Unlike standard repeated-measures analysis of variance, this approach allows for flexibility in the covariance structure of the multiple assessments (a toeplitz structure fit the data best). Like hierarchical linear modeling,<sup>28</sup> this analysis retains all observations, but time intervals are considered fixed. This analysis was applied to the ASI-Drug Use Composite score and the report of cocaine use during the past 30 days, using all patients with any outcome data ( $n = 459$ ). Data from months 1 to 6, 9, and 12 were included in the longitudinal analyses. Overall significant treatment effects for the primary outcome measures were followed by 3 specific contrasts of interest, using a Bonferroni-corrected  $\alpha$  of .02 (.05/3). A priori covariates in all models included site, psychiatric severity, the CPI Socialization scale, and baseline drug use. To evaluate whether treatment effects were different during the

active phase compared with the follow-up phase, a phase factor (months 1-6 vs 9 and 12) was included in the analyses, as well as a term for the phase by treatment interaction.

Treatment-by-site interactions were examined in preliminary models that assessed random terms in a longitudinal analysis using the method described by Verbeke.<sup>29</sup> For the ASI-Drug Use Composite score ( $\chi^2_{1,2} = 1.23$ ;  $P = .40$ ) and for days of cocaine use during the past 30 days ( $\chi^2_{1,2} = 0.34$ ;  $P = .70$ ), there were no significant treatment-by-site interactions. Similarly, preliminary longitudinal analyses, including the 3 individual therapy conditions, revealed no significant therapist random effect for the ASI-Drug Use Composite score ( $\chi^2_{1,2} = 0.41$ ;  $P = .67$ ) or for days of cocaine use within the past 30 days ( $\chi^2_{1,2} = 0.63$ ;  $P = .58$ ). Treatment-by-site interactions and the therapist factor were accordingly dropped from further analyses.

To compare treatment conditions on the number of patients who achieved 1, 2, and 3 consecutive months of abstinence, logistic regression was applied using an intent-to-treat sample (all patients).

A Cox proportional hazards model was used to examine the relation of the treatment condition to attrition (days until drop out), using an intent-to-treat sample and the a priori covariates and interaction terms, as given in the outcome analysis. The number of treatment sessions attended was compared across conditions by a 1-way analysis of variance. The relation between days in treatment and outcome was assessed by a longitudinal mixed model using ASI-Drug Use Composite scores at 6, 9, and 12 months as the dependent variable, covariates as given above, and days until drop out or protocol violation as a main effect predictor and an interaction with the treatment condition.

**Table 1. Number of Patients by Treatment Condition and Site\***

Site	Treatment				Total
	IDC	CT	SE	GDC	
Western Psychiatric Institute and Clinic, Pittsburgh, Pa	30	31	31	31	123
Brookside Hospital, Nashua, NH	33	30	30	31	124
Massachusetts General Hospital, Boston	19	17	18	18	72
McLean Hospital, Belmont, Mass	11	12	13	12	48
University of Pennsylvania, Philadelphia	28	29	32	31	120
<b>Total</b>	<b>121</b>	<b>119</b>	<b>124</b>	<b>123</b>	<b>487</b>

\*IDC indicates individual drug counseling; CT, cognitive therapy; SE, supportive-expressive; and GDC, group drug counseling.

supportive-expressive (SE) psychodynamic therapy,<sup>8,9</sup> was added to group drug counseling (GDC).<sup>10</sup> A third treatment combined individual drug counseling (IDC)<sup>11</sup> with GDC, and the fourth consisted of GDC alone. The main-effect hypotheses were that professional psychotherapy plus GDC (SE + GDC and CT + GDC pooled) would be more efficacious than GDC alone and that IDC plus GDC would yield more improvement than GDC alone.

We also examined the relative efficacy of the 2 psychotherapies (pooled) vs IDC, although no specific main-effect hypothesis was proposed for this comparison. The psychiatric severity interaction hypothesis predicted that patients with high levels of psychiatric severity would show a better response to CT plus GDC and SE plus GDC compared with IDC plus GDC or GDC alone. Based on previous literature suggesting that patients with antisocial personality traits (external coping style) respond better when behavioral and cognitive control strategies rather than insight are used, we hypothesized that patients with antisocial personality traits would improve relatively more in CT plus GDC compared with SE plus GDC.

## RESULTS

### PATIENT CHARACTERISTICS

In this patient sample ( $n = 487$ ), 76.8% were male, 57.9% were white, 39.8% were African American, and 2.2% were Hispanic (**Table 3**). The average age was 33.9 years old. Most patients (69.6%) lived alone, and 60.4% were employed. Patients had completed a mean (SD) of 13.0 (2.0) years of schooling. Most (79.0%) smoked crack, with the remaining using it intranasally (18.9%) or intravenously (2.1%). At the time of

**Table 2. Therapist Characteristics by Treatment Type\***

Characteristic	Treatment			
	SE (n = 13)	CT (n = 15)	IDC (n = 12)	GDC (n = 10)
Age, mean (range), y	38.8 (31-48)	40.0 (31-52)	40.1 (31-49)	42.6 (30-62)
Men	9 (69)	12 (80)	4 (33)	8 (80)
Ethnicity				
White	12 (92)	14 (93)	9 (75)	8 (80)
African American	0	1 (7)	3 (25)	1 (10)
Other	1 (8)	0	0	1 (10)
Degree				
MD	1 (8)	0	0	0
PhD, PsyD, or EdD	9 (69)	12 (80)	0	0
MSW	0	3 (20)	0	1 (10)
MA	3 (23)	0	5 (42)	2 (20)
BA, AA, or RN	0	0	7 (58)	7 (70)
Clinical experience, mean (SD), y	10.3 (4.9)	9.9 (7.4)	10.4 (5.9)	6.9 (5.1)
Estimated No. of patients with substance use disorder treated, mean (SD)	31.5 (30.8)	79.3 (206.1)	333.6 (345.3)	145.2 (123.3)

\*Data are given as number (percentage) unless otherwise indicated. Abbreviations for treatment are given in the footnote to Table 1. MD indicates doctor of medicine; PhD, doctor of philosophy; PsyD, doctor of psychology; EdD, doctor of education; MSW, master of social work; MA, master of arts; BA, bachelor of arts; AA, associate in arts; and RN, registered nurse.

**Table 3. Demographic and Clinical Characteristics of 487 Patients\***

Characteristic	Treatment Group				Total	Site Differences	
	IDC (n = 121)	CT (n = 119)	SE (n = 124)	GDC (n = 123)		Significance	P
White, No. (%)	67 (55.4)	67 (56.3)	77 (62.1)	71 (57.7)	282 (57.9)	$\chi^2_4 = 183.25$	<.001
Employed, No. (%)	74 (61.2)	73 (61.3)	78 (63.4)†	68 (55.3)	293 (60.3)†	$\chi^2_4 = 12.58$	<.01
Living alone, No. (%)	88 (72.7)	85 (71.4)	88 (71.0)	78 (63.4)	339 (69.6)	$\chi^2_4 = 23.27$	<.001
Crack and drug injectors, No. (%)	93 (76.9)	99 (83.2)	105 (84.7)	97 (79.5)†	394 (81.1)†	$\chi^2_4 = 51.25$	<.001
Men, No. (%)	86 (71.1)	98 (82.4)	100 (80.6)	90 (73.2)	374 (76.8)	$\chi^2_4 = 8.86$	.07
Age, y	33.2 (6.7)	34.8 (6.0)	33.3 (6.1)	34.3 (6.3)	33.9 (6.3)	$F_{4,482} = 4.74$	<.001
Education, y	12.9 (2.0)	13.0 (2.0)	12.9 (2.1)	13.1 (1.9)	13.0 (2.0)	$F_{4,482} = 2.77$	.03
ASI Drug Use Composite Score	0.25 (0.07)	0.23 (0.06)	0.23 (0.06)	0.24 (0.07)	0.24 (0.06)	$F_{4,482} = 0.57$	.68
Cocaine use past 30 d, d	10.8 (8.1)	9.9 (7.9)	10.1 (7.2)	11.0 (7.8)	10.4 (7.8)	$F_{4,482} = 1.11$	.35
Cocaine use, y	6.4 (4.5)	7.0 (4.8)	6.8 (4.8)	7.4 (4.9)	6.9 (4.8)	$F_{4,481} = 1.51$	.20
Alcohol use past 30 d, d	7.4 (7.9)	7.7 (7.9)	7.0 (7.7)	7.5 (8.2)	7.4 (7.9)	$F_{4,482} = 2.17$	.07
ASI–Psychiatric Severity Composite	0.18 (0.17)	0.20 (0.20)	0.20 (0.21)	0.18 (0.20)	0.19 (0.19)	$F_{4,482} = 0.80$	.53
Intake CPI Socialization Scale score	22.3 (5.0)	22.2 (5.4)	21.9 (6.1)	22.8 (5.1)	22.3 (5.4)	$F_{4,482} = 3.30$	<.01

\*Data are given as mean (SD) unless otherwise indicated. Abbreviations for treatment are explained in the footnote to Table 1. None of the variables by treatment group were significantly different. ASI indicates Addiction Severity Index; and CPI, California Psychological Inventory.

†Data were not available for 1 patient.

intake, the patients had been using cocaine a mean (SD) of 10.4 (7.8) days and alcohol 7.4 (7.9) days in the previous month. The duration of cocaine use was 6.9 (4.8) years. One third met criteria for alcohol dependence, 4.5% for cannabis dependence, and 17.0% for cannabis abuse. Twenty-eight percent met criteria for a cocaine-induced mood disorder and 4.9% for a cocaine-induced anxiety disorder. Fourteen percent of patients met full criteria for antisocial personality disorder, and another 31.8% met criteria for an antisocial personality disorder as an adult with no history of a childhood conduct disorder. For the 487 patients and the 459 patients with at least 1 postrandomization outcome assessment, there were no significant differences between treatment conditions on sociodemographic variables, baseline ASI–Drug Use

Composite score, the composite psychiatric severity measure, or the CPI Socialization scale score.

In general, the sample had low levels of psychiatric severity. For example, only 17.0% of patients had Hamilton Depression Rating Scale (17-item) scores above 14. The mean ASI–Psychiatric Severity Composite score was 0.19, similar to that of other patients receiving outpatient cocaine treatment<sup>30</sup> and considerably lower than that of opioid-dependent patients.<sup>31</sup>

## ATTRITION

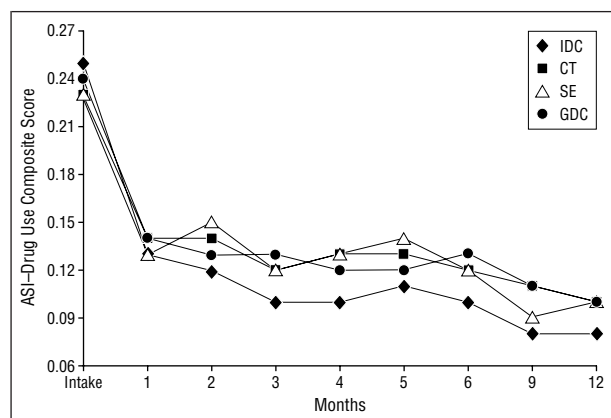
There was a significant difference ( $F_{2,361} = 5.7$ ;  $P = .004$ ) between treatment conditions in the number of individual sessions attended (IDC + GDC mean [SD], 11.9 [10.5]; CT + GDC, 15.5 [10.6]; and SE + GDC, 15.7



**Table 4. Patients Who Dropped Out by Treatment Group\***

Dropout Period	Treatment				Total (N = 487)
	IDC (n = 121)	CT (n = 119)	SE (n = 124)	GDC (n = 123)	
Before 1st session	14 (11.6)	5 (4.2)	6 (4.8)	8 (6.5)	33 (6.8)
Mo 1	43 (35.5)	23 (19.3)	24 (19.4)	41 (33.3)	131 (26.9)
Mo 3	66 (54.5)	47 (39.5)	55 (44.4)	61 (49.6)	229 (47.0)
Mo 6	93 (76.9)	79 (66.4)	83 (66.9)	95 (77.2)	350 (71.9)
Completed treatment	28 (23.1)	40 (33.6)	41 (33.1)	28 (22.8)	137 (28.1)

\*Data are given as number (percentage). Abbreviations for treatment are explained in the footnote to Table 1.



**Figure 1.** Adjusted mean Addiction Severity Index (ASI)-Drug Use Composite scores by treatment condition. At intake, unadjusted ASI-Drug Use Composite scores are reported. For months 1 through 12, scores are adjusted for site, intake number of days cocaine used, intake psychiatric severity, and intake California Psychological Inventory score. IDC indicates individual drug counseling; CT, cognitive therapy; SE, supportive-expressive; and GDC, group drug counseling.

[11.3]). Pairwise comparisons revealed that the number for IDC plus GDC was significantly different from the numbers for CT plus GDC ( $F_{1,361} = 8.48$ ;  $P = .004$ ) and SE plus GDC ( $F_{1,361} = 8.63$ ;  $P = .004$ ). The mean number of group sessions attended was 8.6 (7.2) for IDC plus GDC, 9.5 (7.2) for CT plus GDC, 8.8 (6.8) for SE plus GDC, and 8.6 (7.2) for GDC ( $F_{3,483} = 0.55$ ;  $P = .65$ ).

In addition to dropouts (**Table 4**), 50 patients violated the protocol, with a relatively even distribution across treatment conditions (11 in IDC, 14 in CT, 13 in SE, and 12 in GDC). The most common reason for protocol violation was inpatient substance abuse treatment ( $n = 33$ ), followed by obtaining a prescription for an antidepressant medication ( $n = 8$ ).

Using time until drop out or protocol violation (whichever occurred first) as the dependent variable, a Cox regression model revealed a significant (Wald  $\chi^2_3 = 8.02$ ;  $P = .046$ ) effect for treatment group. The estimated number of days until 50% of patients dropped out or otherwise violated the protocol was 46 days for IDC, 56 days for GDC, 72 days for SE, and 77 days for CT. Pairwise comparisons revealed that patients having IDC

**Table 5. Patients at Each Assessment, by Treatment**

Treatment*	Intake	Month							
		1	2	3	4	5	6	9	12
IDC	121	89	87	85	87	94	92	95	93
CT	119	96	93	86	95	90	97	98	96
SE	124	97	92	88	88	88	91	103	101
GDC	123	98	93	90	93	91	96	100	97
<b>Total</b>	<b>487</b>	<b>380</b>	<b>365</b>	<b>349</b>	<b>363</b>	<b>363</b>	<b>376</b>	<b>396</b>	<b>387</b>

\*Abbreviations for treatment are explained in the footnote to Table 1.

plus GDC had fewer days in treatment than those having CT plus GDC (Wald  $\chi^2_1 = 4.6$ ;  $P = .03$ ).

Using the 6-, 9-, and 12-month scores as dependent variables, days until drop out or protocol violation were not related to the ASI-Drug Use Composite score either as a main effect ( $F_{1,417} = 0.01$ ;  $P = .91$ ) or as an interaction with the treatment condition ( $F_{3,415} = 0.23$ ;  $P = .88$ ). Similarly, days until drop out or protocol violation were not related to the days of cocaine use in the past 30 days at 6, 9, and 12 months as a main effect ( $F_{1,418} = 1.02$ ;  $P = .31$ ) or as an interaction with the treatment condition ( $F_{3,415} = 0.12$ ;  $P = .95$ ).

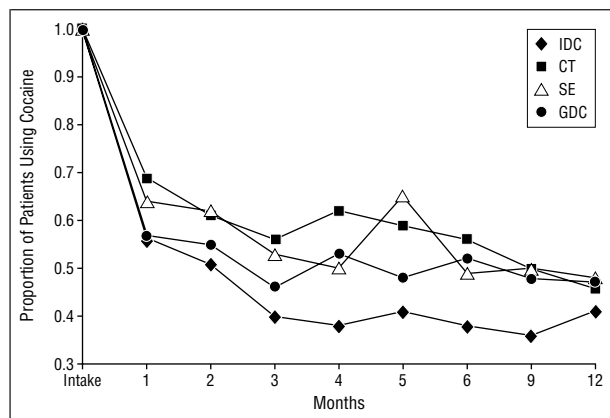
## OUTCOME ANALYSES

### Treatment Main Effects

For the ASI-Drug Use Composite score, a significant effect was evident for treatment ( $F_{3,458} = 3.1$ ;  $P = .03$ ), as well as significant covariate effects for baseline ASI-Drug Use Composite scores ( $F_{1,458} = 31.0$ ;  $P = .001$ ), site ( $F_{4,458} = 9.1$ ;  $P = .001$ ), and psychiatric severity ( $F_{1,458} = 18.4$ ;  $P = .001$ ) but not for the CPI Socialization scale ( $F_{1,458} = 0.05$ ;  $P = .82$ ). The patients in IDC plus GDC had lower average drug use during the 12-month assessment period (**Figure 1** and **Table 5**). Estimated mean ASI-Drug Use Composite scores during months 1 through 12, adjusted for all covariates, were as follows: IDC plus GDC: 0.10, CT plus GDC: 0.12, SE plus GDC: 0.11, and GDC alone: 0.12, with a pooled SD of 0.08. There was also a significant effect for month ( $F_{6,2477} = 3.4$ ;  $P = .003$ ), indicating that all treatments decreased drug use after baseline. Examination of the 3 therapies revealed that IDC plus GDC was significantly better than SE plus GDC and CT plus GDC ( $F_{1,458} = 7.76$ ;  $P = .006$ ) and significantly better than GDC alone ( $F_{1,458} = 6.8$ ;  $P = .009$ ). No difference was found between GDC alone and SE plus GDC and CT plus GDC ( $F_{1,458} = 0.04$ ;  $P = .85$ ).

The analysis of phase revealed a significant main effect ( $F_{1,2477} = 92.2$ ;  $P < .001$ ) but no significant interaction of phase by treatment ( $F_{3,2474} = 1.1$ ;  $P = .35$ ). The main effect for phase was a function of a continued decrease in the ASI-Drug Use Composite scores from months 1 through 6 to months 9 and 12 (Figure 1).

All treatments showed significant improvements from baseline to postbaseline (months 1-12) in cocaine use in the past 30 days ( $F_{6,2503} = 4.3$ ;  $P < .001$ ). Cocaine use in the past 30 days improved from a mean (SD) of 10.4 (7.8) days (median, 8.0; range, 1-30;  $n = 487$ ) at base-



**Figure 2.** Adjusted proportion of patients in each treatment condition who reported any cocaine use in the past 30 days. At intake, all patients had used cocaine in the past month. The proportion of patients who used cocaine during months 1 through 12 was adjusted for site, intake number of days used, intake psychiatric severity, and intake California Psychological Inventory score. The number of patients assessed at each month are listed in Table 5. IDC indicates individual drug counseling; CT, cognitive therapy; SE, supportive-expressive; and GDC, group drug counseling.

line to 3.4 (6.5) days (median, 0; range, 0-30;  $n = 387$ ) at 12 months. A significant main effect of treatment ( $F_{3,458} = 3.2$ ;  $P = .02$ ) showed the greatest improvement for IDC plus GDC. Individual contrasts revealed that IDC plus GDC was better than SE plus GDC and CT plus GDC ( $F_{1,458} = 9.3$ ;  $P = .002$ ), but the other contrasts were not significant (IDC + GDC vs GDC alone [ $F_{1,458} = 2.5$ ;  $P = .11$ ], and GDC alone vs CT + GDC and SE + GDC [ $F_{1,458} = 1.6$ ;  $P = .20$ ]). Because of the distribution problems with this measure, the relative treatment condition effects are best displayed by the adjusted (for covariates) proportion of patients not using cocaine vs those using cocaine (**Figure 2**). By month 6, an estimated 39.8% of the available patients in IDC plus GDC reported the use of cocaine in the past month, whereas 58.2% of patients in CT plus GDC, 50.3% in SE plus GDC, and 52.0% in GDC alone reported cocaine use. At the 12-month follow-up, slightly more patients (40.4%) in IDC plus GDC were using, and slightly fewer patients in the other treatments (46.2% in CT + GDC, 48.3% in SE + GDC, and 46.7% in GDC + GDC) were using cocaine.

To obtain a sense of the clinical importance of treatment effects, the composite cocaine use measure was used to examine the proportion of patients (intent-to-treat sample) in each treatment condition who achieved at least 1, 2, and 3 consecutive months of abstinence (**Table 6**). Considerably more patients achieved and maintained abstinence with IDC compared with those with the other treatments. A significant treatment effect (Wald  $\chi^2_3 = 8.02$ ;  $P = .046$ ) was apparent for 1 month of abstinence, with the contrast of IDC plus GDC to SE plus GDC and CT plus GDC achieving significance (Wald  $\chi^2_1 = 6.7$ ;  $P = .01$ ). Similar results were apparent for 2 and 3 consecutive months of abstinence.

There was no evidence that, for IDC plus GDC, minority therapists had better ASI-Drug Use Composite outcomes with minority patients ( $F_{1,102} = 0.47$ ;  $P = .50$ ) or that counselors in recovery from addiction had better outcomes ( $F_{1,104} = 1.37$ ;  $P = .25$ ). In addition, data on the quality of the therapeutic relationship, as

**Table 6. Estimated\* Percentage of Patients Who Achieved 1, 2, and 3 Months of Consecutive Abstinence From Cocaine Use†**

Consecutive Months Abstinent	Treatment Group, %			
	IDC + GDC (n = 121)	CT + GDC (n = 119)	SE + GDC (n = 124)	GDC (n = 123)
1	71.4	54.1	60.1	58.0
2	48.2	36.0	32.1	42.0
3	38.2	22.9	17.8	27.1

\*Percentages are adjusted for site, baseline psychiatric severity, California Psychological Inventory Socialization scale, and baseline drug use.

†Intent-to-treat sample,  $N = 487$ . Abbreviations for treatment are explained in the footnote to Table 1.

assessed by the California Psychotherapy Alliance Scale and the Helping Alliance Questionnaire at session 2, revealed equally high ratings across the 3 individual treatment conditions and no differences between the conditions (California Psychotherapy Alliance Scale:  $F_{2,300} = 0.2$ ;  $P = .79$ ; Helping Alliance Questionnaire:  $F_{2,298} = 0.5$ ;  $P = .63$ ).

#### Treatment by Intake Psychiatric Severity Interaction

No significant interaction was found between treatment (SE + GDC and CT + GDC vs IDC + GDC and GDC alone) and the baseline psychiatric severity composite score by the change in the ASI-Drug Use Composite score ( $F_{1,459} = 0.23$ ;  $P = .63$ ) or in days used cocaine in the past month ( $F_{1,459} = 0.23$ ;  $P = .63$ ).

#### CT vs SE Interaction With Antisocial Personality Traits or External Coping Style

The effect of the treatment condition on the ASI-Drug Use Composite score ( $F_{1,226} = 0.19$ ;  $P = .66$ ) and days used cocaine in the past month ( $F_{1,226} = 0.43$ ;  $P = .51$ ) did not vary by CPI Socialization scale score.

#### COMMENT

Although the treatments SE plus GDC and CT plus GDC retained patients better, IDC plus GDC produced superior reductions of overall drug use and cocaine use. Relative to the other treatment conditions, a greater proportion of patients in IDC plus GDC achieved abstinence. Despite large differences between sites in baseline characteristics and outcomes, there was no evidence of differential efficacy of the treatments among sites. Although the reason for the superiority of IDC plus GDC is unclear, it may be attributable to its coherent focus on the importance of stopping drug use. Further analysis of mediators of change in this study may yield clues about how IDC plus GDC exerted its effects, particularly in the context of patients in IDC plus GDC attending fewer individual treatment sessions. For example, patients who receive both IDC and GDC may have benefited from an additive effect of a single focus or engaged to a greater extent with outside self-help (eg, Alcoholics

Anonymous) meetings, possibly reducing the need for study treatment sessions.

Previous studies<sup>1,5</sup> comparing the results of professional psychotherapy with those of drug counseling for opiate-dependent patients did not find drug counseling to be superior in reducing drug use. The use of methadone hydrochloride with opiate-dependent patients may be an important difference between the previous studies and this one. The use of methadone might have helped to keep patients stable and in treatment, thereby allowing professional psychotherapy to have a greater effect. Higher rates of psychiatric symptoms were evident in the opiate-dependent trials,<sup>2,3</sup> however, possibly increasing the relevance of psychotherapy. The drug counselors also differed from the CT and SE psychotherapists in several ways—eg, experience with patients with substance abuse disorders—and these differences may have been important in producing differential outcomes.

**T**HE ESPECIALLY strong results in the present study for IDC plus GDC also contrast with previous studies<sup>32,33</sup> that found limited effects of drug counseling for cocaine-dependent patients. In the studies by Higgins et al,<sup>34,35</sup> behavioral treatment produced improvements slightly better than with IDC plus GDC in the present study (65% [11/17] of available patients abstinent from cocaine for the past 30 days in Higgins et al<sup>34</sup> compared with 59.1% [55/93] for IDC plus GDC in the present study), whereas drug counseling produced fewer benefits (46.2% [6/13] abstinent in the past month at 1 year). The patients, however, were dissimilar (eg, greater minority participation in the present study). Also crucial to the understanding of our results is to emphasize that a particular form of high-quality drug counseling was implemented. Individual and group drug counseling were codified in treatment manuals.<sup>10,11</sup> Extensive attention was paid to the selection, training, and competence certification of counselors. Counselors had extensive experience treating patients with substance use disorders. Such experience alone does not explain the results because IDC plus GDC performed significantly better than GDC alone (at least in reducing overall drug use), which also was provided by highly experienced counselors. Another factor to consider is that patients in IDC received intensive treatment, including both individual and group sessions. Greater intensity and quality of treatment may explain the better results found here compared with those of earlier studies<sup>36</sup> with weekly sessions. To the extent that weekly group counseling represents a typical public sector treatment program, our results suggest that a greater intensity of treatment will yield superior benefits.

The nature, intensity, and quality of the IDC plus GDC provided in this project may raise questions about the generalizability of the results. That this study was a multisite investigation with a large sample size and no significant differential treatment effects by site or therapist effects suggests some degree of generalizability to other similarly selected sites, counselors, and patients.

The results do not necessarily generalize to other forms of drug counseling or counseling performed in the community, which vary widely in intensity, quality, and type of interventions. The drug counseling in this project restricted its focus to fundamentals of a 12-step philosophy. In the community, relapse prevention and other techniques are commonly incorporated into drug counseling.<sup>37</sup> Whether such relapse prevention techniques are particularly useful, as found by Carroll et al,<sup>30,38</sup> or whether the best approach is to focus on one intervention—ie, conveying a simple abstinence message through the 12-step philosophy—is an important question raised by our data.

Professional psychotherapy was not shown to be superior among patients with comorbid psychiatric symptoms. Patients with higher levels of psychiatric symptoms achieved poorer outcomes in all treatments; however, our patients had low rates of comorbid psychiatric symptoms. This low rate is consistent with other evidence for declining rates of psychopathological disorders in cocaine-dependent patients.<sup>39</sup> Psychotherapy may be more useful for patients with higher levels of psychiatric symptoms than represented here. A focused drug-counseling approach may be most beneficial in the early phase of treatment and the initiation of abstinence, and psychotherapy for issues that lead to a vulnerability to drug use may be better addressed after a period of abstinence.

No evidence was found that CT, relative to SE psychodynamic therapy, was particularly useful for patients with antisocial personality traits or external coping style. The lack of evidence for this hypothesis contrasts with previous studies of alcoholic patients<sup>40</sup> and other groups<sup>41,42</sup> in which cognitive-behavioral therapies were compared with psychodynamic, interactional, or experiential therapies. In comparing cognitive-behavioral, 12-step facilitation, and motivational enhancement treatments for alcohol dependence, Project MATCH<sup>43</sup> failed to find such an interaction using the same CPI Socialization scale used in the current project. Future research is needed to understand for which treatments and groups antisocial personality traits or external coping style is a relevant patient-treatment-interaction variable.

One limitation of the present study is that low psychiatric severity, in part due to the exclusion of patients who used psychotropic medication, may have hindered the testing of one of our interaction hypotheses. Another limitation is the lack of a biological outcome measure. Although obtaining urine specimens at a frequency that would provide certainty about patients' use of cocaine (cocaine metabolites are typically detectable for  $\leq 3$  days) is difficult, the lack of such an objective measure of cocaine use restricts our results to self-reported cocaine use. Despite generally good agreement between urine test results and self-reports of cocaine use, whether patients were using cocaine at times when no assessments were available is unknown. Another important limitation is that only 52.0% (487/937) of patients who received an intake assessment completed the orientation phase and were randomly assigned to a treatment. Thus, the results of the study are generalizable to only a por-



Coordinating Center, Collaborating Scientists, Clinical Sites, Training Unit, and Monitoring Board

**Coordinating Center:** University of Pennsylvania Medical School, Philadelphia (Drs Crits-Christoph [Principal Investigator], Siqueland [Project Coordinator], and Moras [Assessment Unit Director], Messrs Jesse Chittams and Robert Gallop [Data Management/Analysis], and Dr Muenz [Statistician]). **Collaborating Scientists:** Drs Blaine and Onken, Treatment Research Branch, Division of Clinical and Research Services, NIDA, Rockville, Md. **Clinical Sites:** University of Pennsylvania Medical School (Drs Luborsky [Principal Investigator], Barber [Co-Principal Investigator], and Mercer [Project Director]); Brookside Hospital-Harvard Medical School, Nashua, NH (Drs Frank [Principal Investigator] and Butler [Co-Principal Investigator], Innovative Training Systems) and Ms Bishop [Project Director]); McLean Hospital, Belmont, Mass, and Massachusetts General Hospital-Harvard University Medical School, Boston (Drs Weiss [Principal Investigator], Gastfriend [Co-Principal Investigator], and Najavits and Griffin [Project Directors]); and University of Pittsburgh-Western Psychiatric Institute and Clinic, Pittsburgh, Pa (Dr Thase [Principal Investigator], Mr Daley [Co-Principal Investigator], Dr Salloum [Co-Principal Investigator], and Ms Lis [Project Director]). **Training Unit:** Heads of Cognitive Therapy Training Unit: Dr Beck (University of Pennsylvania Medical School) and Bruce Liese, PhD (University of Kansas Medical Center, Kansas City); Heads of Supportive-Expressive Therapy Training Unit: Drs Luborsky and David Mark, PhD (University of Pennsylvania Medical School); Heads of the Individual Drug Counseling Unit: Dr Woody (Veterans Affairs-University of Pennsylvania Medical School); and Heads of Group Drug Counseling Unit: Dr Mercer (Head), Mr Daley (Assistant Head; University of Pittsburgh-Western Psychiatric Institute and Clinic), and Gloria Carpenter, MEd (Assistant Head; Treatment Research Unit, University of Pennsylvania). **Monitoring Board:** Larry Beutler, PhD, University of California at Santa Barbara; Jim Klett, PhD, independent consultant, Belair, Md; Bruce Rounsaville, MD, Yale University School of Medicine, New Haven, Conn; and Tracie Shea, PhD, Brown University/Butler Hospital, Providence, RI.

tion of patients who might show up initially at a treatment facility.

Our initial follow-up data indicated that patients receiving IDC plus GDC continued to evidence the lowest drug use at 9 and 12 months. Thus, no evidence was found for delayed effects for the psychotherapies, unlike the results reported by Carroll et al.<sup>44</sup> Such an effect may become apparent at longer-term follow-up assessments. Despite that average drug use for the IDC-treated patients remained relatively low throughout the active phase and 9- and 12-month follow-up assessments, sustained abstinence was not achieved by most patients, with only 36% of patients in the IDC-plus-GDC condition achieving 3 consecutive months of abstinence. Further development and testing of treatments of cocaine dependence are indicated to enhance the effects found with manual-driven IDC plus GDC.

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