

Acupuncture for the Treatment of Cocaine Addiction

A Randomized Controlled Trial

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COCAINE ADDICTION CONTINUES to be a serious problem in the United States. The Office of National Drug Control Policy estimates that in 1998 there were 3.3 million chronic cocaine users.¹ Although several psychological and behavioral approaches have shown promise,^{2,3} treatment for cocaine addiction has been impeded by the lack of a generally effective pharmacologic agent. Partly because of this lack, auricular acupuncture as codified by the National Acupuncture Detoxification Association (NADA)⁴ is now one of the most widely used treatments for this disorder, with more than 400 substance abuse clinics

See also Patient Page.

Context Auricular acupuncture is widely used to treat cocaine addiction in the United States and Europe. However, evidence from controlled studies regarding this treatment's effectiveness has been inconsistent.

Objective To investigate the effectiveness of auricular acupuncture as a treatment for cocaine addiction.

Design Randomized, controlled, single-blind clinical trial conducted from November 1996 to April 1999.

Setting Six community-based clinics in the United States: 3 hospital-affiliated clinics and 3 methadone maintenance programs.

Patients Six hundred twenty cocaine-dependent adult patients (mean age, 38.8 years; 69.2% men); 412 used cocaine only and 208 used both opiates and cocaine and were receiving methadone maintenance.

Intervention Patients were randomly assigned to receive auricular acupuncture (n=222), a needle-insertion control condition (n=203), or a relaxation control condition (n=195). Treatments were offered 5 times weekly for 8 weeks. Concurrent drug counseling was also offered to patients in all conditions.

Main Outcome Measures Cocaine use during treatment and at the 3- and 6-month postrandomization follow-up based on urine toxicology screens; retention in treatment.

Results Intent-to-treat analysis of urine samples showed a significant overall reduction in cocaine use (odds ratio, 1.40; 95% confidence interval, 1.11-1.74; $P=.002$) but no differences by treatment condition ($P=.90$ for acupuncture vs both control conditions). There were also no differences between the conditions in treatment retention (44%-46% for the full 8 weeks). Counseling sessions in all 3 conditions were poorly attended.

Conclusions Within the clinical context of this study, acupuncture was not more effective than a needle insertion or relaxation control in reducing cocaine use. Our study does not support the use of acupuncture as a stand-alone treatment for cocaine addiction or in contexts in which patients receive only minimal concurrent psychosocial treatment. Research will be needed to examine acupuncture's contribution to addiction treatment when provided in an ancillary role.

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in the United States and Europe providing this form of treatment.⁵ Auricular acupuncture is also a treatment component in numerous drug court programs.

The mechanism by which acupuncture may treat cocaine addiction is unclear. Clinical reports suggest that it has a calming effect upon patients, decreases craving for cocaine, and promotes retention of patients in psychosocial treatments.⁶ Research on acupuncture for the treatment of cocaine addiction has shown mixed results: some studies have found no difference between the NADA protocol and needle-insertion control,⁷⁻¹⁰ while others have reported promising findings.¹¹⁻¹⁴ The methods used in these studies have varied, further impeding inferences concerning efficacy. Given the widespread use of auricular acupuncture in treating cocaine addiction, a multisite study enrolling individuals who were dependent on cocaine only (primary cocaine users) and on opiates and cocaine and who were receiving methadone maintenance (methadone-maintained) was warranted. We conducted the study from November 1996 until April 1999.

To control for various aspects of the acupuncture treatment context that might influence outcome, we used 2 active control conditions—insertion of needles into non-NADA-specified points and a relaxation condition. Because the investigation of acupuncture is difficult if not impossible to conduct under double-blind conditions, this study was conducted single-blind.¹⁵ In addition, because all of the treatments tested are to some degree active, the study was described to patients as an investigation of various alternative therapies for cocaine addiction, specifically, relaxation and 2 types of acupuncture.

The primary hypotheses of the study were as follows: compared with those in the 2 control conditions, patients assigned to the NADA treatment condition would be more likely to provide negative urine screens throughout the course of the study and at follow-up and

more likely to complete treatment and be retained in treatment longer.

METHODS

Participants

Participants were recruited from 6 sites: 412 from the primary sites (Los Angeles, Calif: n=148; Miami, Fla: n=159; San Francisco, Calif: n=105) and 208 from the methadone-maintained sites (New Haven, Conn: n=83; Minneapolis, Minn: n=50; Seattle, Wash: n=75). The intent-to-treat (ITT) sample comprised the 620 patients who were randomized to treatment. This sample size provided sufficient power (>.80; $\alpha=.05$) to detect a small treatment-effect size (.20) among the treatment conditions on the percentage of urine screens testing positive for cocaine throughout the course of the study, allowing for an overall dropout rate of between 50% (power=.90) and 60% (power=.82), typical of addiction studies.¹⁶ The research protocol was approved by the investigational review boards of each site, and all participants provided written informed consent to participate in the study.

Entrance and Discontinuation Criteria

To be included in the study, participants had to be at least 18 years of age, have been diagnosed with cocaine dependence according to the Structured Clinical Interview for the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (SCID)*,¹⁷ and have evidence of recent cocaine use either by providing a cocaine-positive urine screen at or within 2 weeks before screening or by self-reporting cocaine use in the week before screening. Exclusion criteria were as follows: (1) being dependent on any substance besides opiates, cocaine, or nicotine; (2) currently receiving treatment for cocaine dependence; (3) currently taking a prescription benzodiazepine; (4) currently taking any other psychotropic medication unless maintained on this medication for at least 90 days; (5) currently receiving acupuncture treatment or having had acupuncture in the previous 30 days; and (6)

being actively suicidal or psychotic. Patients who failed to attend 3 of the first 8 sessions or failed to attend at least 1 session weekly thereafter were discontinued from treatment and coded as dropouts.

Randomization

Following completion of the screening and intake interviews, patients were randomized to 1 of the 3 treatment conditions according to a permuted-block, computer-based randomization procedure that balanced each site's sample by sex. Patients were told their treatment assignment and attendance requirements. Treatments were described with a standardized script, encouraging patients to view all of the study treatments as ways to reduce stress, with potential benefits for reducing craving and subsequent cocaine use. Patients assigned to relaxation were also provided with instruction concerning the relaxation protocol. Patients' progress through the trial is illustrated in FIGURE 1.

Treatment Conditions

The treatments have been described in detail elsewhere.¹¹ A brief description of each treatment follows.

NADA Auricular Acupuncture Protocol. Needles were inserted into the auricles bilaterally at 4 points in or near the concha, which are commonly used in addiction treatment: "sympathetic," "lung," "liver," and "shen men." The single-use stainless steel needles (Seirin Co Ltd, Shimizu-City, Japan) were 0.2 mm wide and 15.0 mm long. There were several reasons why we used a 4-needle version of the NADA protocol instead of the 5-needle version that is more widely used in clinical practice. First, we wanted to avoid overstimulating the auricle in the control condition because of controversies concerning whether effects are due to stimulation of specific points or the auricle overall.¹⁸ Second, there is a well-established tradition of using fewer than 5 needles in controlled studies of auricular acupuncture in the addictions.^{7,8,11,14,19} Third, studies using fewer than 5 needles have reported effective-

ness compared with needle-insertion controls, supporting the validity of the 4-needle protocol.^{7,11,14,19} Fourth, there is latitude in the number of needles inserted—the NADA training manual states that the NADA protocol involves the insertion of from “3 to 5 needles into the auricle.”²⁰

Auricular Needle-Insertion Control Condition. Four needles of the same type and size used for the active acupuncture treatment were inserted into the helix of the auricles bilaterally at 3 regions not commonly used for addiction treatment.²¹

Relaxation Control Condition. Patients viewed commercially available videos depicting various relaxation strategies and containing relaxing visual imagery (eg, nature scenes) and soft music.

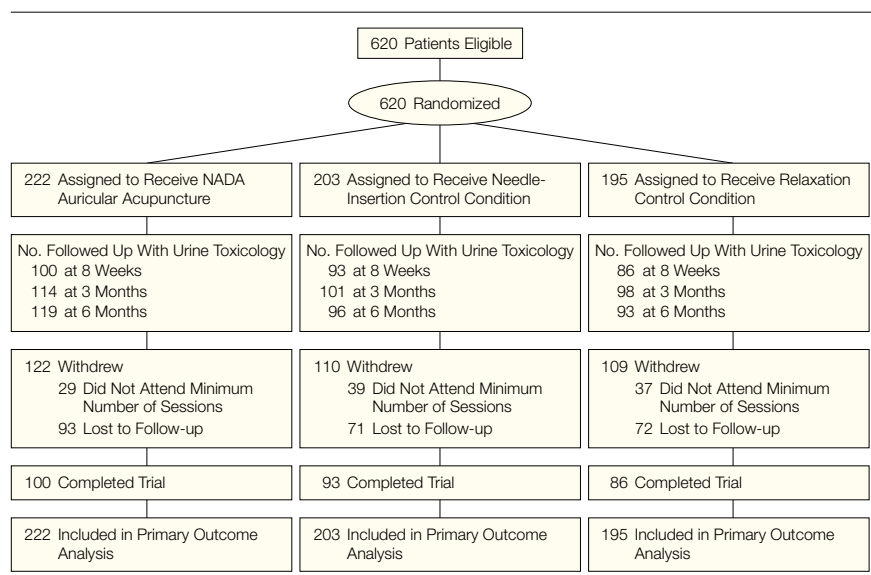
Treatments in the 3 conditions were provided for 40 minutes each week-day for 8 weeks. Patients were encouraged to attend treatment daily. Financial incentives were provided for attendance. Patients received \$2 after each treatment session and an additional \$10 at the end of each week in which at least 2 treatments had been received and 3 urine samples provided. Treatments in all 3 conditions were administered by licensed acupuncturists certified to provide the NADA protocol. The acupuncturists were not permitted to converse with patients. Patients assigned to different treatment conditions were not treated together.

Adjunctive Psychosocial Treatment. At the primary cocaine sites, patients were offered weekly individual counseling sessions according to a treatment manual that was developed for this study and focused on changing addictive behaviors.²² Patients were not discharged from the study for nonattendance. Methadone-maintained patients continued to receive standard methadone maintenance, which included drug counseling.

Assessments

All assessments were conducted by research staff blind to patients' treatment assignment.

Figure 1. Participant Flow Diagram



NADA indicates National Acupuncture Detoxification Association.

Urine Toxicology. The research protocol called for the collection of urine samples 3 times weekly, Monday, Wednesday, and Friday. Missed Monday or Wednesday samples were collected, if possible, the following day. Urine samples were collected from non-completers at the follow-up points but not during the 8-week treatment phase after dropout. The Abbott TDx method (Abbott Laboratories, Abbott Park, Ill) was used to test samples for the presence of cocaine metabolite (benzoylecgonine).²³ Samples containing at least 300 ng/mL were considered positive for cocaine.

Self-reported Cocaine Use. Amount (number of so-called dime bags) and frequency (number of days) of cocaine use and craving for cocaine (scale, 0-10) were assessed in weekly interviews.

Addiction-Related Problems. The Addiction Severity Index (ASI)²⁴ was administered at entry into the trial, at the end of the 8-week treatment phase, and at the 6-month follow-up. The ASI is a structured interview that provides composite scores assessing the severity of 7 addiction-related problem areas: alcohol, drug, employment, family, legal, medical, and psychiatric.

Treatment Readiness and Integrity Readiness for Treatment. The Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES, Version 8D)²⁵ was administered before and after treatment. The scale is a 19-item questionnaire assessing readiness for treatment. Patients are asked to circle numbers on scales from 1 (strongly disagree) to 5 (strongly agree). The readiness composite score ranged from 11 to 71.

Treatment Received. The Treatment Services Review (TSR)²⁶ was administered weekly to monitor treatment services received by patients during the study. The following variables were created by using attendance records and TSR data: total acupuncture sessions, total relaxation sessions, total on-site drug counseling sessions, and total off-site Alcoholics Anonymous, Narcotics Anonymous, and Cocaine Anonymous meetings.

Perceived Credibility of Assigned Treatment. The Treatment Credibility Scale (TCS)²⁷ is a 5-item questionnaire that was administered before and after treatment to assess perceived credibility of the treatment to which the patient was assigned. The scale ranges from 1 (not at all) to 6 (very confident); items were averaged to provide

a single treatment credibility score, with high scores reflecting high treatment credibility.

Therapeutic Alliance. Patient alliance with the acupuncturist–relaxation trainer was assessed with a modified therapeutic alliance scale²⁸ administered at the end of the first treatment session and again in weeks 4 and 8. The 10 items were rated on 7-point scales from 1 (never) to 7 (always) and summed ($\alpha = .94$). Higher scores reflected greater therapeutic alliance (range, 10–70).

Acute Subjective Effects of Treatment Sessions. Acute response to treatment sessions was assessed weekly on 5-point scales from 0 (not at all) to 4 (extreme). The following domains were included: (1) pain and *de qi*–associated sensations (ie, pain in the ears when the needle was inserted, pain at needle sites during the session, warmth in the ears, activity in the ears, and radiating sensations from the ears to the face, neck, or shoulders), (2) relaxation effects relative to pre-session levels (eg, relaxation, heaviness, warmth, sleepiness, and looser muscles), and (3) satisfaction with the session (eg, session enjoyment, stress reduction, feelings of happiness and peacefulness, and increased confidence in acupuncture as a treatment for cocaine problems). Participants were also asked how much they would be willing to pay for such a treatment session in the future (\$0, \$5, \$10, \$15, or \$20). The day after treatment, as a measure of the duration of treatment effects, participants were asked how long the previous session's effects lasted (0 = no effect, 1 = less than 1 hour, 2 = 2–3 hours, 3 = all afternoon, and 4 = all night). Items in each category were averaged.

Analytic Strategy for Data

The 3 conditions were compared on time to dropout with the Kaplan-Meier method and the log-rank test. Examination of differential retention by treatment condition on pretreatment socio-demographic and drug use variables and on perceived treatment credibility, therapeutic alliance, and acute effects of treatment was accomplished with a series of

3 (treatment condition) \times 2 (retention status) analyses of variance on continuous variables and χ^2 analyses by treatment condition and retention status for categorical variables.

The primary outcome analysis, cocaine use based on the thrice-weekly urine samples, was conducted on the ITT sample. SAS PROC GENMOD (SAS Institute Inc, Cary, NC; Version 6.12) was used for the analysis, with each sample coded as positive (1) or negative (0). These data were analyzed by using generalized estimating equations (GEEs) and the z test, as described by Liang and Zeger,²⁹ with the specification of a logit link function, binomial error, and exchangeable working correlation structure. The GEE approach was used for the primary analysis because it is expressly designed to handle repeated measures, intracorrelated binary data with varying numbers at each time point. Secondary analyses included analysis of urine data provided by the subsample of patients who completed the 8-week treatment phase of the study (completers). To determine differential abstinence status at the completion of treatment, χ^2 analyses were conducted by treatment condition on rates of completers whose urine samples were cocaine-negative in week 8. Changes in the ASI severity of addiction composite scores and the SOCRATES readiness for treatment score were also assessed with a series of repeated-measures analyses of variance.

Completeness of Data

The ITT sample provided an average of 2.38 (SD, 0.80) urine samples weekly while participants were in treatment. The treatment completers provided an average of 2.53 (SD, 0.49) urine samples weekly. At the 3-month follow-up, a urine sample was provided by 80.3% (224/279) of the completers and 26.1% (89/341) of the dropouts. At the 6-month follow-up, a urine sample was provided by 74.5% (208/279) of the completers and 29.3% (100/341) of the dropouts. For pretreatment ASI severity of drug problems ($t_{609} = 0.038$, $P = .97$), there was no significant differ-

ence between patients who did and did not provide a follow-up urine screen. Posttreatment ASI data were provided by 94.3% (263/279) of the completers and 41.6% (142/341) of the dropouts; 6-month ASI data were provided by 82.4% (230/279) of the completers and 33.7% (115/341) of the dropouts.

RESULTS

Patient Characteristics

The mean age of the ITT sample was 38.80 (SD, 7.60) years. There were 429 (69.2%) men and 190 (30.6%) women, and there was 1 (0.2%) transgendered person. The sample included 179 (28.9%) whites; 372 (60.2%) blacks; 45 (7.3%) Hispanics; and 22 (3.6%) who identified themselves as “other” minority. Seventy-four (11.9%) had not graduated from high school and 468 (75.5%) were not employed full-time. Patients had used cocaine for an average of 10.94 (SD, 7.10) years. There were no significant differences among the sites or treatment conditions on any pretreatment demographic variable. TABLE 1 provides demographic data by treatment condition.

Checks on Integrity of the Treatment Conditions

Amount of Assigned Treatment Received. Attendance at assigned treatment did not differ significantly across treatment conditions. For the ITT sample, the mean (SD) number of treatment sessions attended was as follows: auricular acupuncture, 15.44 (10.48), needle-insertion control condition, 15.73 (9.54), and relaxation control condition, 14.53 (9.42). For the completed sample, the number of sessions attended was as follows: auricular acupuncture, 23.38 (7.08), needle-insertion control condition, 21.73 (7.15), and relaxation control condition, 20.70 (6.73). Receipt of assigned treatment was generally equivalent across conditions.

Amount of Adjunctive Psychosocial Treatment Received by Treatment Completers. Overall, attendance at psychosocial treatment sessions was poor. Less than 20% of patients reported having an interaction with a coun-

selor each week of the study. More than 50% reported attending less than 1 counseling session each month. Attendance at Alcoholics Anonymous, Narcotics Anonymous, and Cocaine Anonymous meetings was also poor across conditions. Thirty-eight percent of the patients attended no self-help meetings at all while in the study; less than 20% attended such meetings weekly. There were no significant differences by treatment condition on receipt of adjunctive psychosocial services (TABLE 2).

Treatment Credibility and Therapeutic Alliance. There was no significant difference by treatment condition on either treatment credibility ($F_{24,90}=0.749, P=.47$) or therapeutic alliance ($F_{24,97}=1.434, P=.24$). Patients in each condition found the treatments to be credible and reported a positive therapeutic alliance with the treatment provider.

Acute Effects of Treatment Sessions. Relaxation-control patients reported significantly more relaxation effects following their treatment session than did either needle-insertion control patients ($P=.001$) or those assigned to acupuncture ($P<.001$; $F_{25,45}=27.104, P<.001$). There were no significant differences between the 3 treatment conditions on ratings of satisfaction with sessions, duration of treatment effects, or willingness to pay for future sessions. Comparisons between the 2 needle-insertion conditions revealed no significant differences on ratings of pain or *de qi* sensations. Table 2 presents mean scores of measures designed to check the integrity of the treatment conditions for the ITT sample.

Retention

Of the 620 patients who were randomly assigned to treatment conditions, 279 (45%) were retained for the full 8-week trial. Methadone-maintained cocaine users were significantly more likely to complete treatment (63%) than were primary cocaine users (36%; $\chi^2_1=40.888, P=.001$). However, there was no significant difference in the completion rate by treat-

ment condition collapsed across sites: auricular acupuncture, 100 out of 222 patients (45.0%); needle-insertion control condition, 93 out of 203 patients (45.8%); relaxation control condition, 86 out of 195 patients (44.1%). There was no significant difference in the mean (SD) number of weeks patients were retained in treatment: auricular acupuncture, 4.87 (3.19);

needle-insertion control condition, 4.84 (3.28); relaxation control condition, 4.70 (3.28) (log-rank(1)=0.13, $P=.72$). TABLE 3 provides completion rates by treatment condition and site.

There were no significant differences on any pretreatment variable by treatment condition. However, there were differences by retention status. Patients who completed treatment were

Table 1. Summary Statistics of Intent-to-Treat Sample by Treatment Condition*

	Acupuncture (n = 222)	Needle Control (n = 203)	Relaxation Control (n = 195)
Age, mean (SD), y	38 (7.6)	39 (7.7)	39 (7.5)
Sex, % male	70.3	70.9	66.2
Race, %			
White	33.8	25.2	27.3
Black	57.7	62.4	60.8
Hispanic	5.4	8.4	8.2
Other	3.2	4.0	3.6
Employed full time, %	12.5	15.2	8.8
Antisocial personality, %	16.4	14.6	17.1
Drug use, mean (SD)			
Years of cocaine use	10.24 (7.35)	11.69 (6.98)	10.96 (6.88)
"Bags" used weekly	28.8 (103.19)	26.23 (60.50)	31.70 (96.80)
Days used weekly	3.67 (2.37)	3.54 (2.34)	3.31 (2.21)
ASI drug composite score	0.24 (0.09)	0.23 (0.10)	0.27 (0.09)
Route of administration, %			
Intravenous	15.5	16.5	16.9
Smoke	74.0	72.5	70.8
Intranasal	8.2	9.0	9.2

*There were no significant differences between assigned treatment conditions on any assessed pretreatment variable. ASI indicates Addiction Severity Index (drug composite score range, 0-1).

Table 2. Comparability of Conditions During Treatment*

	Acupuncture (n = 222)	Needle Control (n = 203)	Relaxation Control (n = 195)
Sessions attended	15.44 (10.48)	15.73 (9.54)	14.53 (9.42)
Treatment credibility (scale 1-6)	4.22 (1.15)	4.26 (1.25)	4.10 (1.35)
Treatment readiness (possible range, 11-71)	47.48 (8.94)	47.64 (8.48)	47.07 (8.95)
Therapeutic alliance (possible range, 10-70)	56.04 (10.70)	55.02 (11.95)	57.13 (10.21)
Acute effects (scale, 0-4)			
Relaxation effect†	1.62 (0.68)	1.65 (0.70)	2.11 (0.73)
Satisfaction	2.08 (0.75)	2.19 (0.80)	2.45 (0.78)
Willingness to pay	2.06 (1.23)	2.28 (1.27)	2.27 (1.34)
Effect duration	2.20 (1.11)	2.19 (1.03)	2.29 (1.06)
Pain	1.00 (0.61)	0.95 (0.64)	...
<i>de qi</i>	0.93 (0.67)	1.01 (0.76)	...
Other treatment received			
Drug counseling sessions attended	3.62 (5.87)	4.12 (6.75)	3.02 (4.14)
AA/NA/CA meetings attended	4.33 (7.28)	5.21 (13.46)	4.79 (8.66)

*All data are presented as mean (SD). AA indicates Alcoholics Anonymous; NA, Narcotics Anonymous; and CA, Cocaine Anonymous. Ellipses indicate that data were not computed.

†Relaxation control participants reported significantly more relaxation effects following their treatment session than did either needle-insertion control participants ($P=.001$) or patients assigned to acupuncture ($P=.001$; $F_{25,45}=27.104, P=.001$). There were no other differences between treatment conditions.

significantly older (dropped mean [SD]: 38 [7.6]; retained: 40 [7.5] years; $t_{618}=3.58, P<.001$), less likely to be employed full-time (dropped: 15.1%; retained: 8.1%; $\chi^2_1=5.784, P=.01$), more severely addicted as measured by the ASI drug problems composite score (dropped mean [SD]: 0.23 [0.09]; retained: 0.24 [0.10]; $t_{609}=1.984, P=.048$), more likely to use cocaine intravenously (59%) or intranasally (54%) than by smoking (41%; $\chi^2_2=11.91, P=.003$), and less motivated for treatment as mea-

sured by the SOCRATES (dropped mean [SD]: 48.29 [9.20]; retained: 46.32 [8.13]; $t_{605}=2.768, P=.006$). There was no significant interaction between type of cocaine abuser (methadone or primary) and treatment retention on any of these variables.

Cocaine Use During Treatment and at Follow-up

As a condition for entry, all patients had to have used cocaine within 2 weeks of screening; thus, there were no pretreat-

ment differences among the treatment conditions on cocaine use before entry into treatment. TABLE 4 presents percentage of cocaine urine screens testing positive for cocaine metabolite by treatment condition and site during the 8-week treatment phase. Overall, methadone-maintained patients provided a significantly higher percentage of cocaine-positive urine screens (74.9% [30.4%]) compared with primary cocaine users (67.1% [38.0%]; $F_{15,50}=5.309, P=.02$). There were no other differences between these 2 patient groups. Because there were no treatment \times site or treatment \times patient-group interactions, all subsequent outcome analyses are presented collapsed across site and patient group.

As a primary test of treatment effectiveness, GEE was conducted on the urine samples by comparing acupuncture to each of the control conditions in separate analyses, with and without follow-ups, on both the ITT sample and treatment completers. Because these analyses revealed no significant differences between acupuncture and either of the control conditions, we present an overall analysis comparing acupuncture with both control conditions, including the 2 follow-ups. This analysis revealed that collapsed across groups, there was a significant decline in cocaine-positive urine samples ($z=-3.0, P=.002$), with an overall odds ratio for a negative cocaine urine screen of 1.40 (95% confidence interval, 1.11-1.74). However, the difference between acupuncture and the 2 control conditions was not significant ($z=0.005, P=.90$). FIGURE 2 presents urine toxicology results for the ITT sample by treatment condition during the course of the 8-week trial and at the 2 follow-up points.

For the patients who completed the study, we performed an analysis on the percentage of urine samples testing positive during treatment. This test also revealed no significant differences by treatment condition (auricular acupuncture mean [SD], 69.65% [32.80%], needle-insertion control condition, 65.61% [35.73%], and relaxation control condition, 65.23% [36.93%];

Table 3. Patients Randomly Assigned and Retained by Treatment Condition and Site*

	Acupuncture (n = 222)		Needle Control (n = 203)		Relaxation Control (n = 195)	
	Dropped	Completed	Dropped	Completed	Dropped	Completed
Patients by Site, No. (%)						
Los Angeles (n = 148)	40 (83.3)	8 (16.7)	37 (72.5)	14 (27.5)	37 (75.5)	12 (24.5)
Miami (n = 159)	33 (61.1)	21 (38.9)	28 (53.8)	24 (46.2)	26 (49.1)	27 (50.9)
Minneapolis (n = 50)	10 (55.6)	8 (44.4)	11 (57.9)	8 (42.1)	4 (30.8)	9 (69.2)
New Haven (n = 83)	11 (29.7)	26 (70.3)	7 (30.4)	16 (69.6)	9 (39.1)	14 (60.9)
San Francisco (n = 105)	20 (50.0)	20 (50.0)	20 (62.5)	12 (37.5)	23 (69.7)	10 (30.3)
Seattle (n = 75)	8 (32.0)	17 (68.0)	7 (26.9)	19 (73.1)	10 (41.7)	14 (48.3)
Patients by Setting, No. (%)						
Methadone (n = 208)	29 (36.3)	51 (63.8)	25 (36.8)	43 (63.2)	23 (38.3)	37 (61.7)
Primary cocaine (n = 412)	93 (65.5)	49 (34.5)	85 (63.0)	50 (37.0)	86 (63.7)	49 (36.3)
Total (n = 620)	122 (55)	100 (45)	110 (54.2)	93 (45.8)	109 (55.9)	86 (44.1)

*There were no significant differences in retention by treatment condition across sites. However, methadone-maintained cocaine users were significantly more likely to be retained in treatment (63%), regardless of their assigned treatment condition, than were primary cocaine users (36%; $\chi^2_1=40.888, P=.001$).

Table 4. Percentage of Urine Screens Testing Positive for Cocaine Metabolite by Treatment Condition and Site During the 8-Week Treatment Phase*

	Acupuncture (n = 222)		Needle Control (n = 203)		Relaxation Control (n = 195)	
	Dropped	Completed	Dropped	Completed	Dropped	Completed
Screens by Site, % (SD)						
Los Angeles (n = 148)	71.9 (35.3)	30.8 (31.4)	52.8 (42.6)	34.7 (42.4)	66.1 (42.2)	43.7 (39.9)
Miami (n = 159)	79.8 (35.7)	85.6 (23.8)	72.7 (41.5)	76.5 (31.6)	74.4 (36.8)	75.2 (36.3)
Minneapolis (n = 50)	91.7 (18.0)	80.3 (21.4)	88.7 (22.4)	80.4 (32.8)	46.9 (35.1)	74.3 (33.1)
New Haven (n = 83)	89.3 (11.7)	77.9 (29.2)	78.0 (27.1)	86.3 (24.1)	89.2 (19.2)	62.3 (31.9)
San Francisco (n = 105)	67.7 (37.9)	52.0 (36.7)	73.6 (31.9)	72.0 (30.7)	72.1 (35.7)	53.3 (42.6)
Seattle (n = 75)	95.2 (9.4)	71.4 (27.1)	69.7 (37.2)	46.9 (30.9)	67.3 (43.8)	70.0 (33.7)
Screens by Setting, % (SD)						
Methadone (n = 208)	91.9 (13.5)	76.1 (27.1)	80.1 (28.6)	67.8 (33.9)	91.9 (13.5)	76.1 (27.1)
Primary cocaine (n = 412)	73.2 (35.9)	62.9 (36.9)	65.3 (39.8)	63.7 (37.5)	70.3 (38.3)	63.0 (40.2)
Total Patients						
(n = 620)	78.0 (32.7)	69.6 (32.8)	69.3 (37.5)	65.6 (35.7)	70.4 (37.8)	65.2 (36.9)

*There were no significant differences in percentage of urine samples testing positive for cocaine metabolite by treatment condition or site. Overall, methadone-maintained patients provided a significantly higher mean (SD) percentage of cocaine-positive urine screens during treatment (74.9% [30.4%]) compared with primary cocaine users (67.1% [38.0%]; $F_{15,50}=5.309, P=.02$).

$F_{22,76}=0.466$, $P=.63$). There were no significant correlations between the number of treatment sessions attended and the percentage of urine screens positive for cocaine, either overall ($r[279]=0.008$, $P=.90$) or by treatment group (auricular acupuncture: $r[100]=-0.02$, $P=.90$; needle-insertion control condition: $r[93]=0.10$, $P=.35$; and relaxation control condition: $r[86]=-0.09$, $P=.43$).

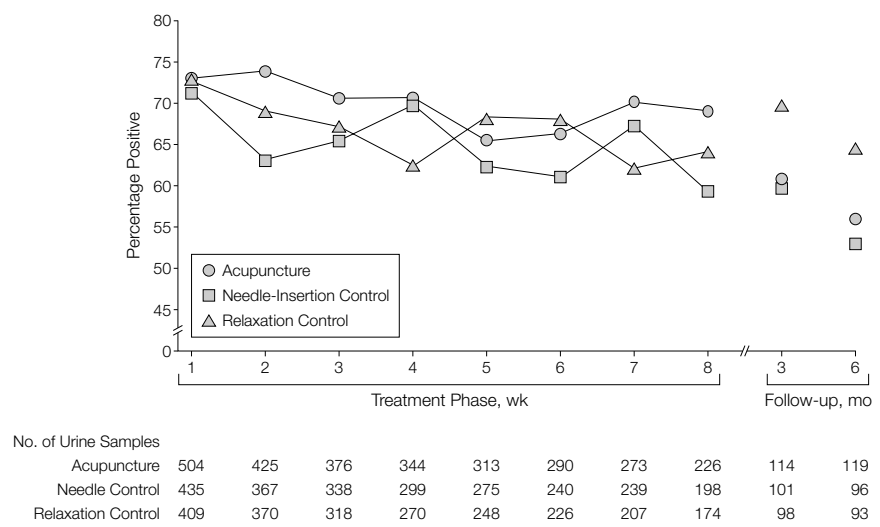
These analyses were repeated controlling for race and sex and again yielded no significant differences by treatment condition. Similar analyses on self-reported amount, frequency of use, and craving for cocaine also yielded no significant differences by treatment condition. Collapsed across treatment conditions, the frequency of cocaine use decreased significantly from a mean (SD) of 14.46 (9.48) days during the month before participants entered the study to 6.43 (9.08) days during the month before the 6-month follow-up ($F_{12,83}=167.77$, $P=.001$).

Abstinence Rates at Treatment Completion and Follow-up. There were no significant differences among the conditions on the percentage of patients not using cocaine by treatment completion or by either of the 2 follow-ups. Rates of abstinence during the final week of treatment by treatment condition were as follows: auricular acupuncture, 23.4% (22/94), needle-insertion control condition, 31.0% (27/87), and relaxation control condition, 28.8% (21/73; $\chi^2_2=1.393$, $P=.50$). Abstinence rates at the 3-month follow-up were as follows: auricular acupuncture, 39.5% (45/114), needle-insertion control condition, 39.6% (40/101), and relaxation control condition, 29.6% (29/98; $\chi^2_2=2.874$, $P=.24$). Abstinence rates at the 6-month follow-up were as follows: auricular acupuncture, 43.7% (52/119), needle-insertion control condition, 46.9% (45/96), and relaxation control condition, 35.5% (33/93; $\chi^2_2=2.689$, $P=.26$).

Severity of Addiction-Related Problems and Treatment Readiness

There were main effects for time for severity of drug problems ($F_{13,93}=200.105$,

Figure 2. Percentage of Cocaine-Positive Urine Screens by Treatment Condition



Overall decrease, odds ratio, 1.40 (95% confidence interval, 1.11-1.74; $P=.002$). The comparison of acupuncture and the control groups was not significant.

$P=.001$), psychiatric severity ($F_{13,94}=20.098$, $P<.001$), legal problems ($F_{14,00}=22.006$, $P=.001$), family problems ($F_{13,94}=17.275$, $P<.001$), and alcohol problems ($F_{13,98}=15.606$, $P=.001$). Severity of drug, psychiatric, legal, family, and alcohol problems decreased significantly from pretreatment to posttreatment, with improvements maintained at follow-up. No significant improvements were found in medical or employment problems or in readiness for treatment. No significant treatment condition \times time interactions were found on any addiction severity measure.

COMMENT

This study did not confirm our initial hypotheses. There were no differences by treatment condition in cocaine use assessed by urine samples or self-report. Throughout the study, there were modest reductions in cocaine use by patients in all 3 conditions. Secondary analyses revealed no significant differences among the treatments on any outcome measure. Relative to patients in the 2 control conditions, patients receiving NADA acupuncture were not retained in treatment longer. Overall rates of cocaine use were comparable to those in

the first 8 weeks of studies of pharmacotherapies in methadone-maintained subpopulations,³⁰ as well as psychotherapies in primary cocaine-addicted subpopulations.² In the addictions, precise comparison with previous acupuncture studies is impeded by varying treatment periods, ancillary counseling conditions, and outcome measures. However, our results are consistent with findings from a large-scale controlled clinical trial⁸ of acupuncture for cocaine addiction in residential and day treatment settings, which also found no difference between the NADA protocol and concurrent controls.

This multisite study was expressly designed to optimize methodologic rigor^{31,32} and included several design features that strengthened its internal validity: (1) objective assessment of the primary outcome variable, cocaine use; (2) the use of 2 active control conditions; (3) checks on treatment credibility; (4) assessment of patient-treater alliance; (5) provision of treatments by certified NADA-trained acupuncturists; (6) sufficient statistical power to detect a small difference in outcome among the 3 conditions; and (7) pretreatment and posttreatment assessment conducted by blind raters. We found no patient bias in fa-

vor of any of the treatments—treatment credibility was equivalent among conditions, as was patient alliance with the treatment provider. Attendance records indicated that, on average, patients in all 3 conditions received comparable treatment. Across conditions, and regardless of dropout status, patients received a clinically appropriate amount of treatment, averaging between 2 and 3 treatments weekly.

We must also note several limitations in this study. Systematic controlled research on a widely used procedural treatment, particularly one whose origins reside outside of a Western biomedical framework, often requires a number of standardizations and alterations that may result in deviations from clinical practice. Our study included the following: use of a 4-needle treatment, while the standard NADA treatment typically involves 5; treatment of research patients in small groups or possibly alone, whereas in NADA clinics patients are more often treated in larger groups; and nonintegration of the study treatments within a comprehensive treatment program, as is recommended in the NADA literature. In designing this study, we regarded these changes as constituting a reasonable compromise among a number of concerns: the need for standardization of the treatment conditions, the need for gaining an estimate of the effectiveness of acupuncture treatments before undertaking more complex investigations examining the interaction between acupuncture and a variety of psychosocial treatments, and given that, as far as we are aware, no study comparing the 5-needle NADA protocol with a 5-needle control has found a difference between the 2 protocols, the need to adequately differentiate the experimental and control needle-insertion conditions while still maintaining the integrity of the experimental treatment. We recognize that any of the alterations noted above could have diminished the internal and external validity of the study. Each betokens an important area of research whose findings would strengthen the

design of clinical trials of acupuncture and would close the gap between research and clinical practice in this area.

Our study used a research design nearly equivalent to that of a previous, smaller study conducted at the Yale site¹¹ in which the same 4-needle version of the NADA protocol delivered for 8 weeks was found to be superior to the 2 control conditions in reducing cocaine use in cocaine-dependent, methadone-maintained patients. In that study, 54% of NADA acupuncture completers provided cocaine-negative urine samples in the last week of the study compared with 23% of acupuncture completers in this study. Patients in the 2 studies assigned to the NADA protocol received approximately the same amount of treatment: 3.5 and 3.0 treatments weekly in the former and current study, respectively. This result raises the question of how to interpret the Yale findings relative to those of this study, including lack of replication at the Yale site. The findings from these 2 studies alone do not yield a definitive answer. Their design was similar, but there were some differences that may have influenced outcome.³³ In our study, standard care included drug counseling as delivered by the methadone program. In the Yale study, standard care also included individual counseling and a once-weekly group therapy session. Another difference is that our study included monetary incentives in the form of cash payments for attendance. Rewarding attendance, rather than abstinence, may have fostered retention of more severely addicted, unmotivated patients, which may have biased findings. Differences in treatment context may have contributed to divergent outcomes between the 2 studies, but it is also possible that our larger study simply provided a better estimate of acupuncture's "true" treatment effect compared with that of the 2 control conditions.

In conclusion, within the clinical context of this study, we did not find acupuncture more effective than a needle insertion or relaxation control in reducing cocaine use. Our study therefore does not support the use of acupuncture as a stand-alone treat-

ment for cocaine addiction or when patients receive only minimal concurrent psychosocial treatments. Research will be needed to examine the contribution of acupuncture when provided in an ancillary role.

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Curiosity is one of the permanent and certain characteristics of a vigorous intellect.
—Samuel Johnson (1709-1784)