

ARTICLE

Auricular Acupuncture in the Treatment of Cocaine Abuse

A Study of Efficacy and Dosing

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Abstract—A single-blind, randomized, placebo-controlled study was performed to evaluate auricular acupuncture (AAc) in the treatment of cocaine addiction. Two linked but concurrent studies were done. In Study 1, residential clients (N = 236) were randomized to true acupuncture (Ac), sham Ac, and conventional treatment without Ac. Treatment group subjects received Ac at three ear points considered to be specific for the treatment of substance abuse (SA). Control subjects received three nonspecific (sham) points. In Study 2, day treatment clients (N = 202) were randomized to one of three dose levels of true Ac (28, 16, or 8 treatments). Subjects received Ac at five, rather than three, specific ear points. Nonspecific (sham) points were not used in Study 2. With rare exception, the data failed to identify significant treatment differences among the true and sham Ac, and psychosocial groups. Furthermore, no differences were observed among the three dose levels of true Ac. © 1998 Elsevier Science Inc.

Keywords—substance abuse; addiction; acupuncture; alternative medicine; cocaine.

INTRODUCTION

RECENT REVIEWS OF cocaine abuse and its treatment are consistent in their estimate of the magnitude of the physical, social, emotional, and economic costs of this affliction (Hatsukami & Fischman, 1996). Also pointed out are the special difficulties related to the treatment of co-

caine abuse (Gawin & Ellinwood, 1988; O'Brien et al., 1988; Smith, 1986). Currently, no particular form of pharmacologic, behavioral, psychosocial, or alternative medicine therapy has been confirmed by research to be the optimal treatment for cocaine abuse (Rawson, Obert, McCann, Castro, & Ling, 1991; Withers, Pulvirenti, Koob, & Gillin, 1995). The general approach of the treatment industry has been to extend treatment methods that are ordinarily applied to alcohol or opiate addiction to cocaine abuse (Hoffman, et al., 1994; Rawson, et al., 1991; Weddington, 1993). The limited success in treating this difficult addiction, however, has encouraged the investigation of other potentially effective methods of treatment (Gorelick, 1993; Mendelson & Mello, 1996).

One of these is auricular acupuncture (AAc), which is the insertion of acupuncture (Ac) needles into prespecified locations in the ear. The historical roots of this

Supported by the National Institute on Drug Abuse, 1 R01 DA07124-01A1.

The authors thank Dan Cain, the Executive Director of the Eden Rehabilitation and Treatment Facility, and the staff and clients of the Eden programs. In addition, we thank Tacey Boucher, Christopher Nolan, Amy Lash-Esau, and Patty Smith-Carlson for their assistance in data collection.

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method are attributed to Wen, who noted that people addicted to opium being treated with postsurgical analgesic electroacupuncture reported relief from withdrawal symptoms (Wen & Cheung, 1973). Since that time, a number of studies of Ac applied to the treatment of heroin, alcohol, nicotine, and cocaine addictions (Avants, Margolin, Chang, Kosten, & Birch, 1995; Bullock, Culliton, & Olander, 1989; Konefal, Duncan, & Clemence, 1994; Lipton, Brewington, & Smith, 1994; Margolin, Avants, Chang, & Kosten, 1993; Margolin, Chang, Avants, & Kosten, 1993; Washburn et al., 1993; Smith, 1988; Wells et al., 1995) have been reported; but few have combined the prerequisites of appropriate sample size, controlled research design, placebo controls and long-term follow-up (Brewington, Smith, & Lipton, 1994; McLellan, Grossman, Blaine, & Haverkos, 1993; Ter Riet, Kleijnen, & Knipschild, 1990).

In the research reported here, variations of an Ac treatment protocol were examined as adjunctive therapy for the treatment of cocaine abuse. A number of key questions were addressed including: (a) Is there an Ac treatment effect over and above that obtained by psychosocial treatment alone?; (b) To what extent does the location of Ac needles make a difference in outcome?; and (c) What are the number of treatments required to produce an Ac effect?

MATERIALS AND METHODS

Setting

Subjects were recruited from the Eden Rehabilitation and Treatment Facility (ERTF), located in downtown Minneapolis, Minnesota. The ERTF is a nationally recognized program providing an array of both residential and outpatient services. The residential program provides treatment for men and women with substance abuse problems, as well as those with dual-diagnosis disorders. Treatment is provided within the framework of a modified therapeutic community in which clients practice newly acquired living skills in a structured and supportive environment. The day program provides services to clients who are experiencing major consequences of their substance abuse and need a treatment experience not requiring a residential setting. Clients live in single resident occupancy housing and are provided with a highly structured, behaviorally based treatment approach augmented by vocational and educational counseling aimed at developing independent living skills.

Over 700 individuals begin treatment for cocaine and other abused substances each year at ERTF. Approximately equal numbers are admitted to the residential and day programs. All patients must be free of illicit substances at the time of admission to the program, as determined by specially trained intake coordinators.

All treatments were delivered, and all data were collected at the ERTF facility.

Subjects

Clients entering the ERTF between April 22, 1992 and December 21, 1995 for the treatment of cocaine dependency were screened for eligibility in this study. Clients were invited to participate if they met each of the following criteria: (a) used cocaine at least two times per week for the month preceding study enrollment; (b) were age 18 or above; (c) were not actively psychotic, suffering neurological, physical, or other mental illness that would impair the ability to comprehend the consent form; (d) were willing to participate in a treatment program involving Ac; and (e) were not receiving antipsychotic, antidepressant, sedative, stimulant, or other mood-altering medications.

Treatment Conditions

This study was a 3-year, single-blind, randomized placebo-controlled trial in which the effectiveness of Ac in the treatment of cocaine abuse was examined. Two concurrent, but linked studies were conducted during this period.

Study 1: Efficacy of Acupuncture with Conventional Substance Abuse Treatment. Residential program clients meeting study eligibility requirements were randomly assigned to one of three treatment groups: (1) conventional multicomponent psychosocial model, (2) conventional plus true Ac, and (3) conventional plus sham (nonspecific) Ac. Clients in groups 2 and 3 of this study were scheduled to receive 28 Ac sessions during a 56-day (8-week) study period. This schedule of treatments was based on the protocol used in our prior investigations.

Study 2: Dose-Response Effect of Acupuncture Therapy. In the second study, clients in the day program were randomly assigned to one of three groups in a dose-response protocol: (1) 28 treatments over 8 weeks, (2) 16 treatments over 8 weeks, and (3) 8 treatments over 8 weeks.

Subjects were randomized to the above treatment conditions after signing the informed voluntary consent forms.

Standardized Ac treatments were given by nationally board certified acupuncturists. Subjects receiving true Ac (Study 1, group 2; Study 2, all groups) received treatment at ear points considered to be specific for substance abuse (see Figure 1). Control subjects (Study 1, group 3) received Ac at nonspecific ear points. The location of all points was confirmed in each subject, at each session, by galvanometric response. Nonspecific points were less than 5 mm from specific points. One wrist point, LI-4 Ho-Ku was also used for all dose-response subjects. Sterile, disposable needles were used, and all Ac points were prepared using 75% alcohol prep pads.

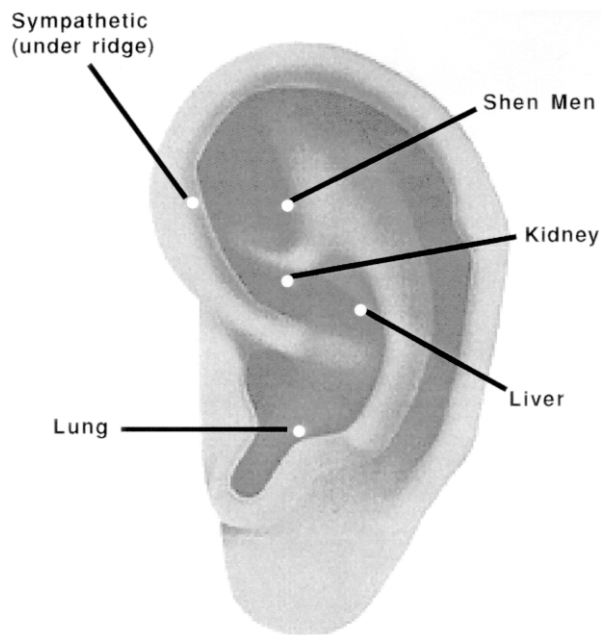


FIGURE 1. Auricular acupuncture points for the treatment of addiction.

Acupuncture treatments were conducted in a large room with subjects seated in comfortable chairs. Up to 15 subjects could be treated simultaneously in this setting. Treatments were administered without manual or electrical stimulation, and lasted approximately 45 minutes. Interaction of the acupuncturist and subjects was limited to the time required for needle replacement and later withdrawal.

Subjects in the dose-response study were treated using five ear points and one wrist point. Subjects in Study 1 were treated using three ear points only.¹

All subjects in the study received the conventional Eden psychosocial programming. Attention was paid to placebo and nonspecific treatment effects; but, with the exception of the Ac treatments, the length of treatment and the particular mix of components was not controlled due to the individualized nature of the treatments themselves.

Dependent Measures

Data collection interviews were conducted by research assistants not affiliated with the ERTF and blinded to the Ac status (true or sham) and dosage levels of the study subjects.

¹The reason that two different treatment protocols (number of needle placements) were used in the day and residential treatment programs is that the acupuncturists believed that five needles in the ear, even if placed at nonoptimal locations, could lead to stimulus generalization because of the sheer number of needle placements. Therefore, only three were used for the true versus sham comparisons. Since all needle placements in the dose-response day treatment study were located in optimal locations, this "stimulus flooding" was not a relevant consideration.

TABLE 1
Instrumentation and Scheduled Administration

Instrument	Scheduled Administration
Addiction Severity Index	Baseline, posttreatment follow-up
Beck Depression Inventory	Baseline, posttreatment follow-up
Medical Outcome Study (SF-36)	Baseline, posttreatment follow-up
Self-Administered Anxiety Scale	Baseline, posttreatment follow-up
Placebo Testing	Baseline
Preference About Therapy	Baseline
Craving Measure	Weekly following last acupuncture treatment
Urinalysis	Weekly on random basis

A number of instruments were employed to gather data regarding our subjects' past and current use of drugs and their demographic and psychosocial characteristics. Instruments, and corresponding schedule of use, are included as Table 1.

Data Analysis

Data were keyed by a professional keypunch vendor using a key and verify technique to enhance the quality of the data. Data were examined for normality by obtaining descriptive statistics and histograms on each of the variables. Appropriate transformations were performed as indicated.

Data were analyzed using a mixed-model analysis of variance that addressed the interaction of the treatment by time effects. Positive and negative urinalysis results were treated as nominal variables in contingency table analyses that examined differences among the treatments at intake and at last day of treatment.

The most conservative analytic option for missing data in the intention to treat (ITT) sample is to substitute baseline values of that subject for the missing data. This procedure biases the outcome in favor of no treatment effects. In our study, however, the results of the analyses using ITT as opposed to treatment completers were, with rare exceptions, essentially the same. In the following presentation of results, ITT analyses will be used and the exceptions noted.

All procedures used in this study were approved by the Institutional Review Board of the Minneapolis Medical Research Foundation/Hennepin County Medical Center.

RESULTS

During the recruitment period for this study, 1017 individuals began treatment for cocaine abuse in the ERTF. After screening, 482 of these individuals were consid-

TABLE 2
Sample Demographics

Variables	<i>M</i>	<i>SD</i>	Missing	Frequency	Percent
Quantitative					
Age	30.2	6.0	15		
Education (in months)	11.6	1.9	2		
Categorical					
Gender					
Male				306	69.9
Female				132	30.1
Race					
White				93	21.2
Black				292	66.7
American Indian				11	2.5
Puerto Rican				1	0.2
Cuban				3	0.7
Other				36	8.2
Missing				2	0.5
Marital status					
Married				43	9.8
Not currently married				105	24.1
Never married				286	65.3
Missing				4	0.8
Employment income (last 30 days)					
\$0				287	65.5
\$1–500				100	22.9
\$500+				47	10.7
Missing				4	0.9
Total income (last 30 days) ^a					
\$0				33	7.5
\$1–500				148	33.8
\$500+				241	55.0
Missing				16	3.7
Number of criminal convictions					
0				91	20.8
1				66	15.1
1–4				125	28.5
5+				138	31.5
Missing				18	4.1

^aTotal income includes income from employment, unemployment compensation, DPA, pension, benefits, social security, money obtained from mate, family or friends, and money obtained illegally.

ered eligible for recruitment. Of these, 438 agreed to participate (91%). In the residential program, 236 subjects were randomly assigned to the three treatment groups. For the day program, 202 subjects were randomized to one of three dose-response groups. Characteristics of subjects in the two studies are shown in Table 2.

Attrition

During the course of the two studies, 162 (37%) of the subjects completed the study, 97 in the residential program; 65 in the day program. The largest number of non-completers ($n = 142$; 32%) removed themselves from the study by leaving the ERTF against the advice of their counselors. The other 134 who failed to complete were excluded from further participation in the study because

of protocol violations ($n = 73$), placement on prescription medications contraindicated for this study ($n = 19$), failure to adhere ERTF rules ($n = 36$), and other nonspecific reasons ($n = 6$). It is notable that only six subjects dropped out because of the rigors of data collection, or because they found the Ac treatments to be uncomfortable. No differences were observed in overall attrition between residential and day program patients ($\chi^2 = 0.62$, $p = .43$), nor between treatment groups within studies (Study 1: $\chi^2 = 3.80$, $p = .15$; Study 2: $\chi^2 = 1.17$, $p = .56$).

Craving

Over the 8-week treatment period, no treatment by time interaction was observed for self-reported cocaine craving

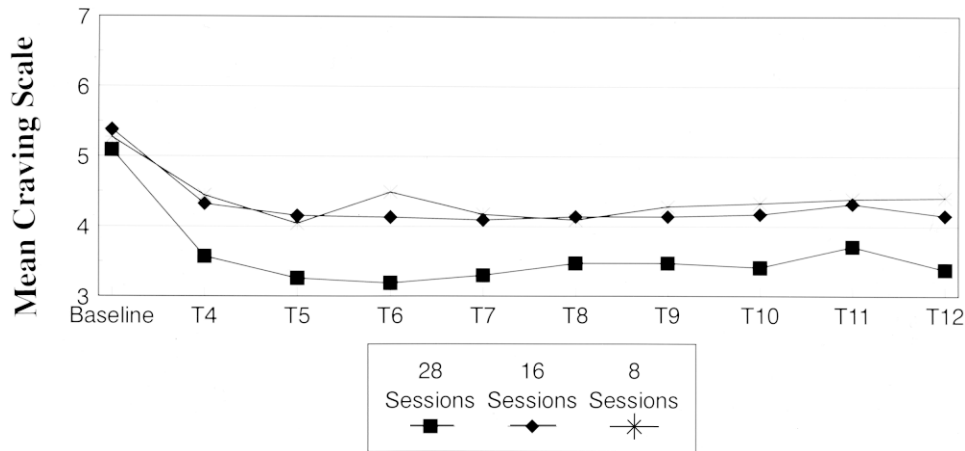


FIGURE 2. Craving measure comparison of three different doses of acupuncture treatment delivered over a period of 12 weeks. Intention to treat data. Note: Treatment × Time Interaction Effect, $p = .89$; Treatment Effect, $p = .11$; Time Effect $p < .01$.

ing in the previous 7 days for Study 1 subjects ($f = .68, p = .83$). Similarly, no dose by time interaction effect was observed in the Study 2 subjects ($F = .59, p = .91$). In both studies, a significant time effect was observed ($F = 17.26, p = .001$; $F = 13.66, p < .001$, respectively), with the change predominately occurring during the first 2 weeks of the study (Figures 2 and 3).

Urine Analysis

For the ITT design, and the most conservative reporting of results, we assumed that subjects who failed to complete the study would have positive urine screens at follow-up, and would be considered treatment failures. Using these criteria, no differences were observed between baseline and endpoints for positive urine tests between the different dosing schedules of 28 treatments (62% positive), 16 treatments (74% positive), and 8 treatments

(73% positive [$\chi^2 = 2.69, p = .26$]). The prevalence of positive urine tests at follow-up in Study 1, however, found that both true (68% positive) and sham (65% positive) acupuncture had less desirable outcomes than psychosocial treatment (45% positive) alone ($\chi^2 = 10.07, p = .007$).

Functional Outcomes

While several functional outcomes were used within this study, all showed similar patterns, with no interaction effect being observed between treatment condition and time for either Study 1 or Study 2. Significant time effects were observed on most measures across all treatment groups. Example results using the Medical Outcome Study (SF-36) and the scales from the Addiction Severity Index are shown in Tables 3 and 4, respectively.

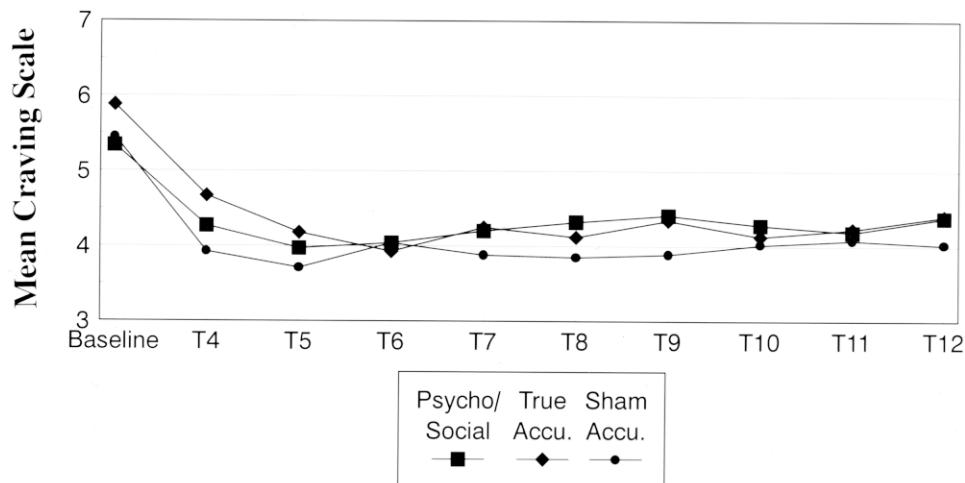


FIGURE 3. Craving measure comparison of true acupuncture, sham acupuncture, and psychosocial treatment alone. Note: Treatment × Time Interaction Effect, $p = .83$; Treatment Effect, $p = .73$; Time Effect, $p = .01$.

TABLE 3
Medical Study (SF-36) Outcomes by Study and Treatment Group

Scale Name		Number of Sessions						<i>p</i> *
		28		16		8		
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	
Study 1								
Physical functioning	Pre	0.77	0.26	0.83	0.21	0.83	0.19	.12
	Post	0.77	0.28	0.82	0.22	0.87	0.17	
Role limits: Physical	Pre	0.56	0.44	0.62	0.39	0.59	0.42	.99
	Post	0.62	0.43	0.67	0.39	0.67	0.38	
Role limits: Emotional	Pre	0.40	0.43	0.48	0.42	0.47	0.43	.08
	Post	0.57	0.45	0.56	0.41	0.50	0.43	
Energy/fatigue	Pre	0.45	0.22	0.48	0.19	0.50	0.19	.83
	Post	0.51	0.24	0.53	0.19	0.54	0.18	
Emotional well-being	Pre	0.51	0.20	0.50	0.20	0.55	0.20	.76
	Post	0.59	0.23	0.58	0.22	0.62	0.21	
Social functioning	Pre	0.46	0.25	0.47	0.20	0.51	0.24	.53
	Post	0.46	0.25	0.51	0.20	0.52	0.22	
Pain	Pre	0.57	0.31	0.66	0.27	0.66	0.28	.56
	Post	0.63	0.31	0.69	0.27	0.68	0.26	
General health	Pre	0.60	0.22	0.65	0.20	0.68	0.22	.71
	Post	0.63	0.23	0.68	0.21	0.72	0.21	
		Treatment Condition						
		True		Sham		Psychosocial		
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>p</i> *
Study 2								
Physical functioning	Pre	0.83	0.26	0.81	0.22	0.77	0.24	.26
	Post	0.82	0.28	0.82	0.24	0.77	0.26	
Role limits: Physical	Pre	0.66	0.36	0.58	0.39	0.62	0.40	.47
	Post	0.68	0.37	0.64	0.40	0.68	0.37	
Role limits: Emotional	Pre	0.44	0.43	0.49	0.44	0.39	0.43	.67
	Post	0.52	0.45	0.56	0.44	0.51	0.45	
Energy/fatigue	Pre	0.45	0.22	0.50	0.19	0.46	0.19	.96
	Post	0.55	0.21	0.56	0.19	0.52	0.20	
Emotional well being	Pre	0.53	0.21	0.48	0.20	0.48	0.20	.98
	Post	0.60	0.22	0.55	0.21	0.55	0.23	
Social functioning	Pre	0.43	0.24	0.46	0.26	0.48	0.23	.50
	Post	0.52	0.24	0.49	0.24	0.50	0.22	
Pain	Pre	0.70	0.25	0.62	0.26	0.63	0.23	.54
	Post	0.73	0.23	0.69	0.24	0.68	0.25	
General health	Pre	0.69	0.21	0.64	0.22	0.64	0.22	.45
	Post	0.70	0.21	0.67	0.22	0.67	0.24	

*Probability value associated with the time by treatment interaction effect.

DISCUSSION

A number of descriptive and controlled studies have suggested that successful treatment of cocaine addiction can be achieved by using AAc as adjunctive therapy (Margolin, Avants, Kosten, & Chang, 1993; Margolin, Chang, Avants, & Kosten, 1993). Lipton, Brewington, & Smith (1994), however, tested this possibility more rigorously with their randomized, placebo-controlled trial, but were unable to detect statistically significant differences between their Ac treatment and control groups regarding any of the outcomes measured, with the exception of urine metabolite levels.

The analysis of our study data, with rare exception, also failed to identify significant differences in treatment

efficacy among our true and sham Ac, dose response, and psychosocial groups. While these results may suffice for some to conclude that Ac has no substantive role in the treatment of cocaine addiction, such a conclusion would be premature without consideration of several difficult methodological issues encountered by those involved in Ac substance abuse (SA) research.

This research was designed to meet most of the requirements of contemporary randomized, placebo-controlled research. Securing funding for a large-scale SA study involving Ac without attention to this prevailing design paradigm could not have been successful. Throughout the study, however, our Ac colleagues

TABLE 4
Addiction Severity Scale Outcomes by Study and Treatment Group

Scale Name			Number of Sessions						<i>p</i> *
			28		16		8		
			<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	
Study 1									
Medical status	Pre		0.56	0.29	0.54	0.27	0.53	0.26	.07
	Post		0.50	0.30	0.48	0.26	0.56	0.25	
Employment status	Pre		0.60	0.23	0.51	0.23	0.61	0.20	.84
	Post		0.63	0.21	0.53	0.19	0.61	0.18	
Alcohol use	Pre		0.64	0.22	0.61	0.24	0.59	0.27	.97
	Post		0.60	0.25	0.57	0.25	0.55	0.28	
Drug use	Pre		0.27	0.09	0.27	0.11	0.26	0.11	.26
	Post		0.26	0.11	0.25	0.11	0.23	0.12	
Psychiatric status	Pre		0.38	0.16	0.42	0.19	0.42	0.16	.31
	Post		0.36	0.16	0.40	0.19	0.38	0.14	
Legal status	Pre		0.35	0.21	0.45	0.22	0.36	0.18	.53
	Post		0.31	0.19	0.41	0.22	0.30	0.21	
Family social status	Pre		0.45	0.17	0.47	0.19	0.44	0.22	.73
	Post		0.43	0.18	0.47	0.19	0.42	0.18	
			Treatment Condition						
			True		Sham		Psychosocial		
			<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>p</i> *
Study 2									
Medical status	Pre		0.54	0.26	0.51	0.29	0.54	0.26	.92
	Post		0.53	0.24	0.50	0.28	0.52	0.27	
Employment status	Pre		0.49	0.20	0.61	0.19	0.53	0.23	.31
	Post		0.56	0.19	0.62	0.19	0.60	0.21	
Alcohol use	Pre		0.58	0.19	0.65	0.22	0.53	0.26	.41
	Post		0.56	0.19	0.62	0.25	0.53	0.26	
Drug use	Pre		0.28	0.09	0.26	0.10	0.26	0.10	.23
	Post		0.25	0.11	0.23	0.11	0.25	0.10	
Psychiatric status	Pre		0.39	0.15	0.46	0.17	0.41	0.16	.50
	Post		0.39	0.15	0.42	0.17	0.39	0.16	
Legal status	Pre		0.31	0.23	0.36	0.24	0.32	0.27	.16
	Post		0.26	0.23	0.28	0.24	0.29	0.27	
Family social status	Pre		0.41	0.19	0.42	0.20	0.46	0.20	.14
	Post		0.38	0.17	0.42	0.21	0.45	0.20	

*Probability value associated with the time by treatment interaction effect.

pointed out that the controlled Ac treatment protocols, which permitted no day-to-day individualization of treatments, grossly distorted the customary practice of their discipline.

Despite our effort to achieve a well-designed study, certain limitations need to be mentioned. For example, it was not possible to withhold treatments other than Ac from subjects in the study, especially the psychosocial treatments, which are widely considered to be the industry's standard of care. Therefore, we were not able to determine the potential effects of spontaneous recovery or, more importantly, the effect of Ac alone.

An additional limitation of our study was that post-treatment follow-up was not pursued. Posttreatment follow-up was not considered appropriate since Ac effects could not be demonstrated during treatment, and it was

unlikely that an effect would manifest itself only after completion of therapy.

The fact that our acupuncturists could not be blinded as to the nature of the treatment being delivered might also be considered a limitation. Constraints such as placing a helmet on the subject or a sheet to separate the subject from the acupuncturist were considered; but while such restrictions might help to isolate needle placement, it has little to do with the actual practice of this treatment, and would therefore have limited generalizability.

The completion rate of 37% is a special problem in this research. The rate is comparable to that found in other studies dealing with cocaine abuse in inner-city populations. On one hand, using the ITT analytic design to handle this problem guards against overinflated estimates of general treatment effects, and provides a "real-

world” view of the benefit of adding AAC to existing psychosocial programs. On the other hand, this same design limits the ability to quantify the treatment effect, if any, in those subjects who do complete the protocol.

Perhaps the most perplexing dilemma in the application of controlled research to Ac treatment of SA is the contrast between our negative findings and the persistent belief of the therapists, treatment subjects, and program administrators that Ac is desired and has perceived benefits that were not demonstrated in our research. Perhaps the fact that subjects who completed the study tended to show improvement on nearly all measures of the treatment they received contributed to this perception of efficacy. These perceptions might be mistaken, or be based on placebo effects, but further research should be done to enhance the understanding of this intriguing paradox.

In this study, we attempted to adhere to the standards of contemporary research design in order to gain a measure of credibility for our results. It may be, however, that the randomized, placebo-controlled paradigm is not the appropriate one for this stage of Ac research. If the entity under investigation is the actual practice of an alternative medicine treatment, then perhaps that treatment should be delivered in its optimal form and only then, if found promising, be analytically dissected into its component parts for separate examination.

In our current alcohol research, we are including a research component that permits therapy to be administered in its optimal format, a “black box” of treatments deemed appropriate by the therapists for a particular subject on a given day. Since neither the mechanisms nor the treatments of alternative medicine are that well understood or precisely described, this more flexible approach should be incorporated into the design of additional studies before the judgment is made that Ac is ineffective for treating cocaine and other drugs of abuse.

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