

# Acupuncture for the Treatment of Cocaine Addiction

## A Randomized Controlled Trial

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**C**OCAINE 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.<sup>1</sup> Although several psychological and behavioral approaches have shown promise,<sup>2,3</sup> 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)<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup> 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,<sup>7-10</sup> while others have reported promising findings.<sup>11-14</sup> 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.<sup>15</sup> 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.<sup>16</sup> 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)*,<sup>17</sup> 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.<sup>11</sup> 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.<sup>18</sup> Second, there is a well-established tradition of using fewer than 5 needles in controlled studies of auricular acupuncture in the addictions.<sup>7,8,11,14,19</sup> Third, studies using fewer than 5 needles have reported effective-

ness compared with needle-insertion controls, supporting the validity of the 4-needle protocol.<sup>7,11,14,19</sup> 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.”<sup>20</sup>

**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.<sup>21</sup>

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

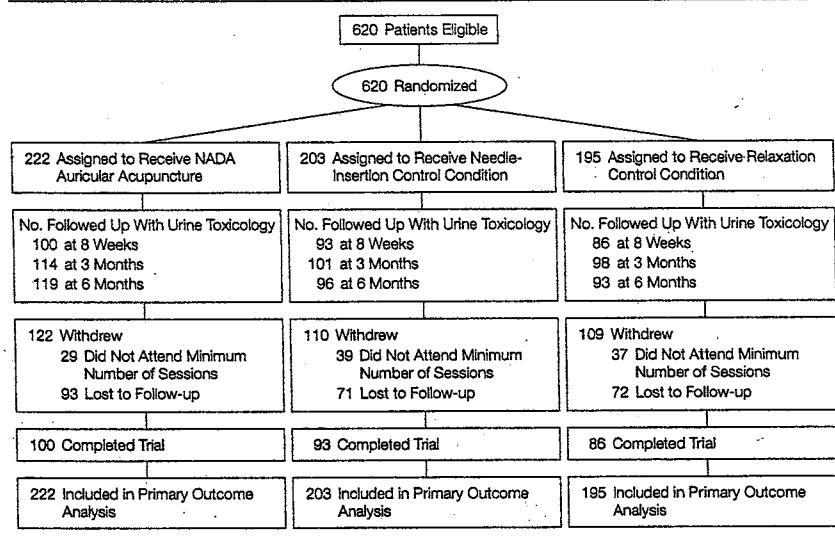
Treatments in the 3 conditions were provided for 40 minutes each weekday for 8 weeks. Patients were encouraged to attend treatment daily. Financial incentives were provided for attendance. Patients received \$2 after each treatment session and an additional \$10 at the end of each week in which at least 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.<sup>22</sup> 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).<sup>23</sup> 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)<sup>24</sup> 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)<sup>25</sup> 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)<sup>26</sup> 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)<sup>27</sup> 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 scale<sup>28</sup> 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 sociodemographic 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  $\chi^2$  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,<sup>29</sup> 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,  $\chi^2$  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)
<b>Total (n = 620)</b>	<b>122 (55)</b>	<b>100 (45)</b>	<b>110 (54.2)</b>	<b>93 (45.8)</b>	<b>109 (55.9)</b>	<b>86 (44.1)</b>

\*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:  $r[86]=-0.09$ ,  $P=.43$ ).

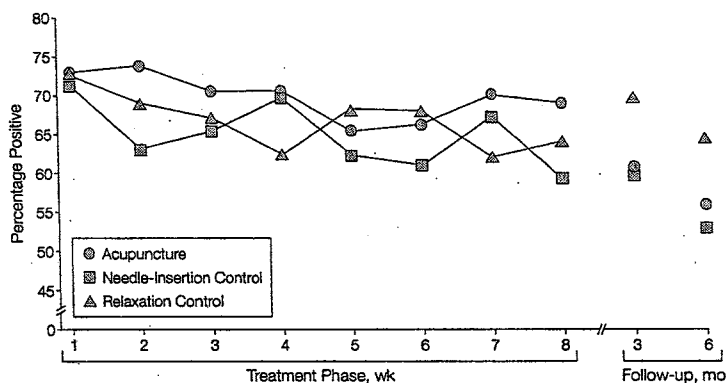
These analyses were repeated controlling for race and sex and again yielded no significant differences by treatment condition. Similar analyses on self-reported amount, frequency of use, and craving for cocaine also yielded no significant differences by treatment condition. Collapsed across treatment 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



No. of Urine Samples	1	2	3	4	5	6	7	8	3 mo	6 mo
Acupuncture	504	425	376	344	313	290	273	226	114	119
Needle Control	435	367	338	299	275	240	239	198	101	96
Relaxation Control	409	370	318	270	248	226	207	174	98	93

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,<sup>30</sup> as well as psychotherapies in primary cocaine-addicted subpopulations.<sup>2</sup> 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 trial<sup>8</sup> 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<sup>31,32</sup> 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 site<sup>11</sup> 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.<sup>33</sup> 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.

**Author Contributions:** *Study concept and design:* Margolin, Kleber, Avants, Konefal, Gawin, Stark, Sorensen, Wells, Jackson, Culliton.

*Acquisition of data:* Margolin, Kleber, Avants, Konefal, Gawin, Stark, Sorensen, Midkiff, Wells, Jackson, Bullock, Culliton, Boles.

*Analysis and interpretation of data:* Margolin, Kleber, Avants, Gawin, Stark, Bullock, Vaughan.

*Drafting of the manuscript:* Margolin, Kleber, Avants, Vaughan.

*Critical revision of the manuscript for important intellectual content:* Margolin, Kleber, Avants, Konefal, Gawin, Stark, Sorensen, Midkiff, Wells, Jackson, Bullock, Culliton, Boles.

*Statistical expertise:* Margolin, Avants, Vaughan.

*Obtained funding:* Margolin, Kleber, Avants, Gawin, Stark, Sorensen.

*Administrative, technical, or material support:* Margolin, Kleber, Avants, Sorensen, Wells, Jackson, Boles. *Study supervision:* Margolin, Kleber, Avants, Konefal, Gawin, Stark, Sorensen, Wells, Culliton.

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Curiosity is one of the permanent and certain characteristics of a vigorous intellect.

—Samuel Johnson (1709-1784)



Substance Abuse Adult Outpatient Services

Agency	Program Name	Modality	Target Population	Number of Static slots	Cost Per Static Slot	Average Cost per Static Slot*	General Fund		Subtotal by Category
							Program Amount	Program Amount	
Walden House AARS	Multi-Services ADAPT	Day Tx	Multi-Diag. Adults	25	\$ 14,026		\$ 350,654		
		Intensive O/P	Adult API Stimulant	11	\$ 26,907		\$ 295,973		
SFGH Westside	STOP Inner City	Intensive O/P	Abusers Adults	15	\$ 23,817		\$ 270,262		
		Intensive O/P	Multi-Diag. Adults	18	\$ 17,946		\$ 253,034		
Westside BVHP	New Directions Center for Problems Dnkr	Dual Dx Outpatient	Adults	14	\$ 17,955		\$ 251,367		
		Outpatient	Adults	12	\$ 22,302		\$ 240,635		
Haight Ashbury Haight Ashbury Haight Ashbury Jelani	ODF Alcoholic Treatment Services Glide Adult Outpatient ODF	Outpatient	Multi-Diag. Adults	36	\$ 27,420		\$ 837,758		
		Outpatient	Adults	8	\$ 17,479		\$ 139,830		
		Outpatient	Adults	25	\$ 14,687		\$ 367,177		
		Outpatient	Adults	16	\$ 18,641		\$ 253,257		
Positive Directions Walden House	Af. Am. Families O/P Continuing Care	Outpatient	Adults	16	\$ 16,412		\$ 262,600		
		Outpatient	Adults	16	\$ 17,844		\$ 285,502		
<b>Totals</b>				<b>212</b>		<b>\$ 19,747</b>	<b>\$</b>	<b>\$ 3,808,049</b>	



# Methadone Maintenance vs 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence

## A Randomized Controlled Trial

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**I**N 1997, THE MOST RECENT YEAR FOR which data are available, treatment program admissions for opioid dependence surpassed admissions for cocaine abuse in the United States.<sup>1</sup> As heroin use resurfaces, evaluation and improvement of the treatment of opioid abuse are increasingly urgent needs. Methadone maintenance treatment (MMT) has been shown to improve life functioning and decrease heroin use; criminal behavior; drug use practices, such as needle sharing, that increase human immunodeficiency virus (HIV) risk; and HIV infection.<sup>2,3</sup> However, variations in efficacy have been reported, and high illicit drug use rates in those undergoing treatment have been observed.<sup>4,5</sup>

Most data about MMT efficacy are from program evaluation efforts, including the Drug Abuse Reporting Project,<sup>6</sup> the Treatment Outcome Prospective Study,<sup>7</sup> and a nationwide study completed by the Department of Veterans Affairs,<sup>8</sup> all of which reported reduction in drug use and criminality following treatment.

See also pp 1337 and 1343 and Patient Page.

**Context** Despite evidence that methadone maintenance treatment (MMT) is effective for opioid dependence, it remains a controversial therapy because of its indefinite provision of a dependence-producing medication.

**Objective** To compare outcomes of patients with opioid dependence treated with MMT vs an alternative treatment, psychosocially enriched 180-day methadone-assisted detoxification.

**Design** Randomized controlled trial conducted from May 1995 to April 1999.

**Setting** Research clinic in an established drug treatment service.

**Patients** Of 858 volunteers screened, 179 adults with diagnosed opioid dependence were randomized into the study; 154 completed 12 weeks of follow-up.

**Interventions** Patients were randomized to MMT (n = 91), which required 2 hours of psychosocial therapy per week during the first 6 months; or detoxification (n = 88), which required 3 hours of psychosocial therapy per week, 14 education sessions, and 1 hour of cocaine group therapy, if appropriate, for 6 months, and 6 months of (non-methadone) aftercare services.

**Main Outcome Measures** Treatment retention, heroin and cocaine abstinence (by self-report and monthly urinalysis), human immunodeficiency virus (HIV) risk behaviors (Risk of AIDS Behavior scale score), and function in 5 problem areas: employment, family, psychiatric, legal, and alcohol use (Addiction Severity Index), compared by intervention group.

**Results** Methadone maintenance therapy resulted in greater treatment retention (median, 438.5 vs 174.0 days) and lower heroin use rates than did detoxification. Cocaine use was more closely related to study dropout in detoxification than in MMT. Methadone maintenance therapy resulted in a lower rate of drug-related (mean [SD] at 12 months, 2.17 [3.88] vs 3.73 [6.86]) but not sex-related HIV risk behaviors and in a lower severity score for legal status (mean [SD] at 12 months, 0.05 [0.13] vs 0.13 [0.19]). There were no differences between groups in employment or family functioning or alcohol use. In both groups, monthly heroin use rates were 50% or greater, but days of use per month dropped markedly from baseline.

**Conclusions** Our results confirm the usefulness of MMT in reducing heroin use and HIV risk behaviors. Illicit opioid use continued in both groups, but frequency was reduced. Results do not provide support for diverting resources from MMT into long-term detoxification.

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Despite such evidence that MMT is a useful treatment for opioid dependence, it remains controversial because of the indefinite provision of a dependence-producing medication. An effective alternative treatment that did not involve indefinite opioid use would be a valuable addition to the limited array of options available to treat heroin dependence.

Short-term methadone detoxification treatment, usually 21 days in duration, was proposed as an alternative to MMT but had poor retention and high relapse rates.<sup>9-11</sup> Long-term detoxification (up to 180 days) was approved in 1989 as a treatment option for opioid-dependent individuals who either do not meet the federal guidelines for MMT or who reject this treatment.<sup>12</sup>

The present study was done to determine whether 180-day methadone-assisted detoxification (M180), when enriched with intensive psychosocial services and aftercare, could provide an efficacious alternative to MMT. Data indicate that psychosocial services increase methadone treatment efficacy.<sup>13,14</sup> We reasoned that adding such services to M180 would provide a reasonable alternative to MMT.

If M180 exceeded or matched MMT in efficacy, it might provide a viable alternative treatment. On the other hand, if M180 did not equal MMT in efficacy, this study would provide additional and convincing evidence for the value of MMT.

## METHODS

### Participants

The study was publicized by notices, word-of-mouth, and written information. Participants met *Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition (DSM-III-R)* criteria for a diagnosis of opioid dependence and had an initial urine screening test result positive for an opioid other than methadone and negative for methadone. Potential participants were excluded if they had medical conditions that contraindicated methadone treatment or a psychiatric condition that interfered with treatment, were enrolled in substance abuse treatment, had been in a methadone treatment program within the previous week or were in the follow-up phase of a previous methadone detoxification research protocol, could not be expected to remain in the study for 12 months, did not have signs of opioid withdrawal on 3 occasions, or were younger than 18 years. Women of childbearing age were required to be practicing birth control. A pregnancy test was administered, and those pregnant or breastfeeding were excluded. Participant disposition from initial contact to trial completion is shown in FIGURE 1.

The research took place at the San Francisco Veterans Affairs Medical Center, San Francisco, Calif. Veterans were not eligible because MMT is available on request for clinically appropriate veterans at the same site. The study was

approved by the University of California, San Francisco, Committee on Human Research.

### Assessments

Participants were assessed at baseline and monthly for 12 months. A urine specimen was collected at each assessment.

During the first 6 months, urine samples were collected weekly from participants in both study groups. In the second 6 months, 1 urine specimen was collected monthly in the M180 group and weekly in the MMT group. The differential collection of urine specimens during the second 6 months in the 2 groups reflected the anticipated difficulty of obtaining weekly urine specimens from participants in the M180 group, who no longer had the incentive of methadone to encourage them to return to the clinic. In both groups during both 6-month blocks, 1 urine sample per month from each participant was selected for data analysis.

Urine specimens were analyzed by enzyme-multiplied immunoassay technique for the presence of cocaine, heroin, amphetamines, barbiturates, benzodiazepines, tetrahydrocannabinol, and methadone.

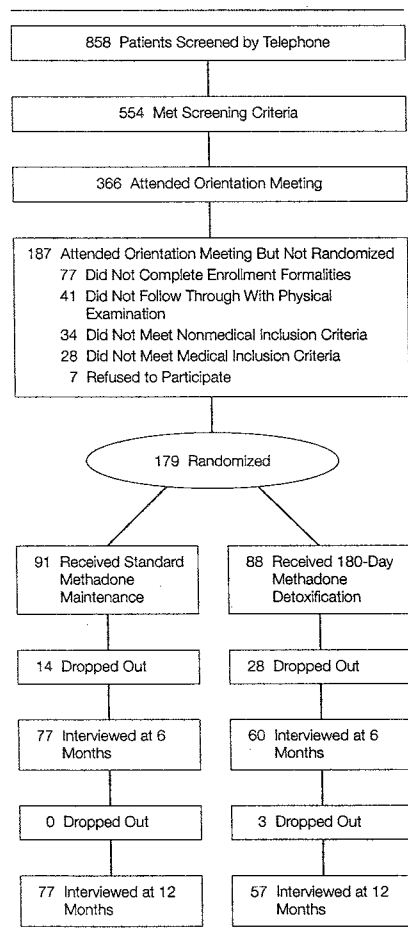
### Outcome Measures

Opioid use was coded as negative if the participant indicated no illicit opioid use in the last 30 days and the urine screening test result was negative for opioids other than methadone. Cocaine use was coded as negative if the participant indicated no cocaine use in the last 30 days and the urine screening test result was negative for cocaine.

The Addiction Severity Index (ASI)<sup>8,15</sup> assesses functioning in employment, drug use, alcohol use, legal, family, and psychiatric problem areas. It was administered monthly by research interviewers.

The computerized Diagnostic Interview Schedule<sup>16-19</sup> was administered at baseline. We obtained DSM-III-R lifetime diagnoses for alcohol and drug abuse or dependence disorders, post-traumatic stress disorder, major depressive disorder, dysthymic disorder, and antisocial personality disorder.

**Figure 1.** Patient Flow Diagram



The Risk of AIDS Behavior (RAB) scale<sup>20</sup> assesses drug use and sexual behaviors that increase risk for HIV infection over a 6-month period. It was administered at enrollment and 6 and 12 months.

The Treatment Services Review (TSR)<sup>21</sup> is a structured interview that provides information on the type and number of services received in each ASI problem area. We developed 2 parallel forms, 1 for services received from the research program (in-program) or from an outside provider (out-of-program). The TSR was scored by summing the number of services received in-program and out-of-program separately.

### Enrollment

Individuals who met screening criteria, gave written informed consent, and completed enrollment procedures were further evaluated by medical history and physical examination. If eligibility criteria were met, participants completed a baseline assessment. They then came to the clinic on the day before the admission day to provide a urine specimen. Those who returned the following day in opioid withdrawal were stratified by sex and ethnicity, randomly assigned from stratified blocks to either M180 or MMT, and began treatment. The randomization assignments were generated via computer software by the project statistician using varying block sizes known only to the statistician and were kept in sealed envelopes.

Participants in both groups were required to attend an HIV risk reduction education class and a session describing the program. They were given a detailed community resource manual and appropriate referrals.

### Follow-up

Research interviewers located and assessed participants. Individuals who missed appointments were contacted by telephone and mail. When necessary, interviewers used contact information to find participants and interview them in the community. Interviews took 35 to 90 minutes to complete. Respondents were paid \$15 for each of the first 5 interviews, \$35 for assessments occurring in

months 6 through 11, and \$50 for the 12-month interview. If participants completed all assessments for months 6 through 11, a \$50 bonus was given at 12 months; thus, participants could earn \$100 for the final interview. To increase the probability of locating participants, participants were paid \$20 for verified changes in locator information.

### Treatment

In both groups, the initial methadone dosage was 30 mg/d, increased to 80 mg/d within the first 3 treatment weeks. The maximum methadone dosage was 100 mg/d, reached by day 44. Participants could be evaluated for an increase in methadone dosage at any time if the current dosage was less than 100 mg/d or for a lower dosage if the participant had consistent opioid-free urine screening test results. Methadone dosages were adjusted based on test results. Breath tests for alcohol content were conducted if alcohol intoxication was suspected.

Dosing occurred 7 days a week, with take-home medication provided on holidays. Participants who missed medication for 3 consecutive days were reevaluated before restarting treatment. Participants who missed medication for 7 consecutive days were discharged from treatment.

### Counselors

Counselors had master's degrees in social work or behavioral sciences and a minimum of 4 years of counseling experience and were supervised by a psychiatrist and psychologist. The same staff treated patients in both groups. Assessments were conducted by research interviewers.

### Early Discharge

Early discharge occurred if a participant violated program rules (eg, criminal behavior on hospital grounds), failed to attend treatment program activities, requested discharge or transfer, or was incarcerated.

### Methadone Maintenance

In the MMT group, participants were eligible for 14 months of methadone main-

tenance, followed by a 2-month detoxification. Fourteen months of maintenance were provided to assess the effects of maintenance (at month 12) before the potential psychological effects of impending detoxification. Participants were required to attend 1 hour per week of substance abuse group therapy for the first 6 months of maintenance and 1 hour per month of individual therapy. After the first 6 months, group attendance was optional. Participants who failed to comply with treatment requirements were discharged.

Twenty-four MMT participants were discharged for failure to attend clinic or comply with program rules. Eleven were jailed, 1 elected a self-taper, and 1 transferred to another program. Of the 24 discharges, 15 applied for and were readmitted at least once.

### 180-Day Methadone Detoxification

In M180, participants were eligible for 14 months of substance abuse treatment. During months 1 through 6, 120 days of induction or maintenance were followed by 60 days of dosage reduction. During the first 6 months of treatment, participants were required to attend 2 hours per week of substance abuse group therapy, 1 hour per week of cocaine group therapy if cocaine was noted on their admission urine screening test result and 2 subsequent screening test results (continued attendance was required until urine specimens tested cocaine-free for a month), a series of 14 weekly 1-hour substance abuse education classes, and weekly individual therapy sessions.

During months 7 through 14, participants were offered 8 months of aftercare (nonmethadone) treatment that included weekly individual and group psychotherapy and liaison services with the criminal justice system, medical clinics, and social service agencies.

Forty M180 participants were discharged for failure to attend clinic or comply with program rules. Ten were jailed and 6 transferred. Most discharges were participants who failed to appear for the last few detoxification doses.

Participants who failed to comply with treatment recommendations or re-

quested early detoxification were not eligible to restart methadone treatment. However, they were eligible to receive nonmethadone substance abuse treatment, and 14 did so.

**Statistical Methods**

Sample size was based on a type I error rate of .05, a type II error rate of .20, nondirectional testing, and effect sizes found in relevant literature and pilot data. Analyses were based on an intent-to-treat model with all collected data used in analyses—complete-case-only analyses were not used.

Treatment retention was the number of days between study enrollment and the last day a participant received any psychosocial service. Heroin and cocaine use was measured by self-report of abstinence or use, with abstinence confirmed by the monthly urinalysis screening tests. For participants who had provided more than 1 urine specimen per month, the specimen collected nearest to the interview (within 4 days before or after the scheduled monthly assessment) was tested.

The RAB subscale scores assessing HIV-related drug and sexual risk behaviors over the past 6 months served as measures of HIV risk behaviors. The number of times a participant reported using a needle to inject drugs in the week before the assessment was used as a second indicator of drug-related HIV risk behavior. Psychosocial functioning was determined by ASI composite scores in 5 problem areas: psychiatric, family, legal, employment, and alcohol use. Treatment services used, both in-program and out-of-program, were assessed using the TSR.

Retention in treatment was tested using Kaplan-Meier survival estimates and a Wilcoxon signed rank test to compare the groups. For all other hypotheses, a treatment group by assessment generalized linear model was the prototypical model. While all participants were scheduled for monthly assessments, the actual time they were interviewed varied around the scheduled date by 7 days. In the data-analysis models, the assessment point (days from enrollment) was treated as

a continuous time-varying covariate. Study participants dropped out of treatment and from assessment interviews over time. The resulting missing data were not imputed; rather, the models used all observed data at each assessment for parameter estimation. Tests were based on the marginal effects using the generalized estimating equation approach<sup>22</sup> with a 1-step autoregressive covariance structure. SAS, version 6.12, GENMOD procedure (SAS Institutes, Cary, NC) was used to estimate and test all models. For models with a dichotomous outcome (eg,

drug use), a binomial distribution with logit link function was used; for counts, a Poisson distribution with log-link function was used ( $\alpha = .05$  for all tests).

**RESULTS**  
**Demographic, Drug Use, and Diagnostic Characteristics**

As shown in TABLE 1, there were no significant differences between groups at baseline for demographic, drug use, diagnostic, HIV-risk, or psychosocial functioning variables, with 1 exception: alcohol abuse or dependence ( $\chi^2_1$ , 5.54;  $P = .02$ ).

**Table 1.** Demographic Characteristics, Drug Use, and Lifetime Psychiatric Diagnosis by Treatment Condition\*

Characteristic or Diagnosis	Treatment Group	
	180-d Methadone-Assisted Detoxification (n = 88)	Methadone Maintenance Treatment (n = 91)
<b>Demographic Characteristics</b>		
Age, mean (SD), y	39.4 (7.91)	39.4 (8.57)
Men	53 (60)	52 (57)
Race/ethnicity		
White	46 (52)	46 (50)
African American	23 (26)	31 (34)
Hispanic	15 (17)	8 (9)
Other	4 (5)	6 (7)
High school education	69 (78)	64 (70)
Employed	42 (48)	42 (46)
Married	18 (20)	19 (21)
Living situation		
With family or friends	74 (84)	76 (84)
Alone	10 (11)	9 (10)
No stable living arrangements	4 (5)	4 (4)
Controlled environment	0 (0)	2 (2)
<b>Drug Use</b>		
Heroin use		
Years, mean (SD)	15.7 (9.26)	16.6 (9.42)
Grams/wk	6.8 (4.73)	7.2 (8.65)
Lifetime incarceration, mo	54.8 (66.59)	54.0 (74.52)
Illegal income in past 30 d, mean (SD), \$	1696 (2276)	1353 (1659)
Employment income in past 30 d, mean (SD), \$	926 (1299)	786 (1210)
<b>Diagnosis</b>		
Posttraumatic disorder	26 (30)	27 (30)
Major depression	23 (26)	16 (18)
Dysthymic disorder	10 (11)	9 (10)
Antisocial personality disorder	32 (36)	32 (35)
Alcohol abuse or dependence	61 (69)	47 (52)†
Cocaine abuse or dependence	44 (50)	45 (49)
Nicotine dependence	62 (70)	72 (79)

\*Data are presented as number (percentage) unless otherwise indicated.  
† $P = .02$ .



The M180 participants were more likely to be diagnosed as having an alcohol abuse or dependence disorder. Alcohol disorder was not a significant predictor of any outcome variable. Comparison of baseline values of outcome measures among participants who dropped out before the final assessment vs those who remained produced only 1 significant difference: dropouts had lower mean RAB drug risk scores ( $P = .05$ ).

Across groups, cocaine use at enrollment was nonsignificantly related to less time in treatment ( $P = .09$ ). Also, the greater the percentage of cocaine positive assessments, the fewer the days in treatment ( $P = .02$ ), an association that was significantly stronger in the M180 ( $r = 0.35$ ;  $P < .001$ ) than in the MMT group ( $r = 0.06$ ;  $P = .59$ ).

#### Methadone Dose During Treatment

To compute the average methadone dose received by each participant, we excluded doses before day 17 (the induction phase) and, for the M180 group, doses received after day 120 (the taper phase). Also excluded were doses taken under an early taper (eg, a taper due to rule violations) and clinic-withheld doses. We assumed that unobserved doses such as take-home or hospital inpatient doses were taken as scheduled. Eight individuals who participated only in the induction phase (4 in each group) were omitted. Mean methadone dose in the 2 groups did not differ (M180 group [ $n = 84$ ], mean [SD], 85.3 [12.01] mg/d; MMT group [ $n = 87$ ], mean [SD], 86.3 [12.88] mg/d;  $t_{169}$ , 0.52;  $P = .60$ ).

The number of services used in each group was computed to determine whether, as planned, M180 participants did receive more in-program services than MMT participants during the first 6 months of the study. As shown in FIGURE 2, group, assessment, and group-by-assessment effects for the TSR in-program score were all statistically significant. The significant interaction reflected the fact that the M180 group used more services during months 1 through 4 than the MMT group, and fewer dur-

ing months 5 through 12. Assessment and group-by-assessment effects were significant for out-of-program scores, but the group main effect was not. Participants in the 2 groups did not differ markedly in out-of-program services during the first 5 months of the study, but beginning at month 6, the M180 participants reported more use of out-of-program services.

#### Retention

As shown in FIGURE 3, group time in treatment differed. The MMT participants remained in treatment longer (median days, 438.5; 95% confidence interval [CI], 413-441) than the M180 participants (median days, 174.0; 95% CI, 161-181).

The 2 conditions also differed in the proportion of participants available at each monthly assessment (Wilcoxon  $\chi^2$ , 8.58;  $P = .01$ ). Sample size available at each monthly assessment declined over time to a low at the month 11 assessment (75/91 MMT [82.4%] and 52/88 M180 participants [59.1%]). At the month 12 assessment, there were 77 MMT and 57 M180 participants.

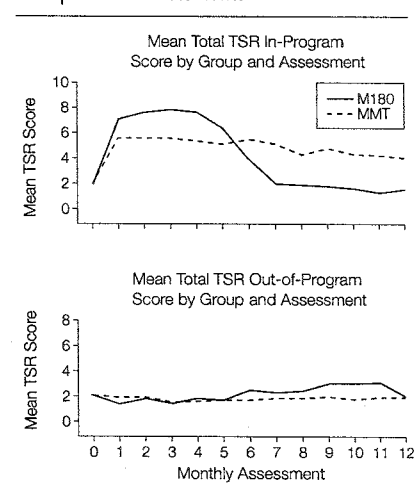
At each time point ( $t$ ) there was no correlation between the results of the urine screening test for heroin and the probability of the participant being present for assessment ( $t + 1$ ). There was a negative relationship between the proportion of heroin-positive urine screening test results and the number of days in treatment ( $r^2$ , 0.10;  $P < .001$ ) that, while statistically significant, explained so little of the variance that it was unimportant for clinical purposes. Given the consistently high levels of continued heroin use and the lack of a lag-1 correlation between heroin use and the probability of dropout, we treated the missing data as random in the sense that they were not related to the unobserved outcome variable.

#### Illicit Opioids

Neither group nor assessment effect was significant for opioid use. Group-by-assessment interaction reached the  $P < .05$  level of significance. As FIGURE 4 shows, participants in the 2 treatment

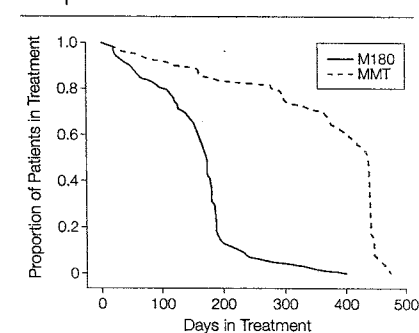
groups differed little until month 5, when use rates for the M180 group increased markedly and remained greater than that of the MMT group until month 12. Reanalyzing these data under the assumption that the missing data were drug-positive did not produce any important differences from the analysis that

**Figure 2.** Mean TSR In-Program and Out-of-Program Scale Scores by Treatment Group Across Assessments



TSR indicates Treatment Services Review; M180, 180-day methadone-assisted detoxification; and MMT, methadone maintenance treatment. Robust parameter estimates ( $P$  value) for in-program: group,  $-0.32$  ( $< .001$ ); assessment,  $-0.006$  ( $< .001$ ); and group by assessment,  $0.003$  ( $< .001$ ). Robust parameter estimates ( $P$  value) for out-of-program: group,  $0.07$  (.62); assessment,  $0.003$  (.001); and group by assessment,  $-0.003$  (.01).

**Figure 3.** Survival Function by Treatment Group



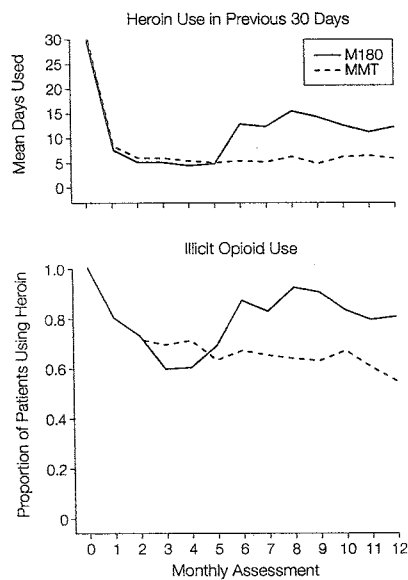
Proportion of study participants in treatment by group over time. M180 indicates 180-day methadone-assisted detoxification; MMT, methadone maintenance treatment. For significant differences between conditions, Wilcoxon  $\chi^2$ , 85.0 ( $P < .001$ ).

did not impute heroin use. Illicit opioid use rates were greater than 50% for both groups at any assessment.

As a second index of heroin use, we analyzed days of heroin use in the pre-

vious month, as reported on the ASI. Effects for assessment, group, and group-by-assessment were significant. Heroin use in both groups markedly decreased from baseline, but the decrease was greater in the MMT group during the last 6 months of treatment (Figure 4).

**Figure 4.** Proportion of Participants Using Heroin and Mean Days of Heroin Use in Previous 30 Days



M180 indicates 180-day methadone-assisted detoxification; MMT, methadone maintenance treatment. Robust parameter estimates (*P* value, <.001 for all estimates): group, -0.15; assessment, -0.005; and group by assessment, 0.003.

**HIV Risk Behaviors**

The RAB drug-risk subscale scores indicated a significant group by assessment interaction; at months 6 and 12, the level of HIV drug-risk behavior reported by MMT participants was lower than that reported by M180 participants. Group and assessment main effects were not significant. There were no significant effects on the RAB sex-risk behaviors scale (TABLE 2).

For the number of times participants reported injecting heroin in the week before each assessment, neither the main effects for group or assessment were significant, but the group-by-assessment interaction was significant and favored less needle use in the MMT group during months 6 through 12.

**Psychosocial Functioning**

No significant effects for group-by-assessment were found for the ASI psychiatric and family composite scores, which were uniformly low across time,

or the employment composite score, which was uniformly high. The ASI legal composite score was uniformly low with a mean of 0.20 or less at all assessments. There were no significant assessment or group main effects for legal composite scores, but the assessment-by-group interaction was significant. From 6 months on, the M180 participants reported significantly higher legal composite scores than did the MMT participants, although the magnitude of differences and the low absolute level suggest that the finding may be of little clinical importance.

**Cocaine Use**

Statistically significant differences were found for assessment and assessment by group. During months 4 through 7 and 9 through 12, M180 participants had lower cocaine use rates than MMT participants. Main effects for group were not significant. Interpretation of these data was confounded by differences between the 2 groups in the strength of the relationship between days in treatment and cocaine use, with cocaine users more likely to drop out of M180 than MMT.

There is little basis for assuming that a missing assessment should be counted as positive for cocaine for all missing participants. To examine the stability

**Table 2.** ASI Composite Scores and Risk of AIDS Behavior Scale at Enrollment, 6 Months, and 12 Months by Treatment Group\*

Variable	Mean (SD) Scores					
	Enrollment		At 6 Months		At 12 Months	
	M180 (n = 88)	MMT (n = 91)	M180 (n = 60)	MMT (n = 77)	M180 (n = 57)	MMT (n = 77)
<b>ASI Composite Scores</b>						
Medical	0.17 (0.277)	0.22 (0.336)	0.11 (0.254)	0.19 (0.293)	0.14 (0.292)	0.20 (0.31)
Employment	0.77 (0.227)	0.81 (0.254)	0.79 (0.248)	0.82 (0.257)	0.76 (0.251)	0.77 (0.262)
Alcohol use	0.09 (0.145)	0.09 (0.161)	0.08 (0.137)	0.10 (0.197)	0.05 (0.099)	0.11 (0.208)
Drug use	0.37 (0.092)	0.37 (0.088)	0.27 (0.146)	0.25 (0.135)	0.17 (0.145)	0.18 (0.151)
Legal status	0.19 (0.213)	0.20 (0.202)	0.16 (0.200)	0.08 (0.167)	0.13 (0.193)	0.05 (0.130)
Family or social status	-0.03 (0.192)	-0.06 (0.178)	-0.12 (0.154)	-0.09 (0.184)	0.14 (0.086)	0.15 (0.113)
Psychiatric	0.15 (0.179)	0.15 (0.171)	0.15 (0.222)	0.15 (0.194)	0.11 (0.205)	0.15 (0.189)
<b>Risk of AIDS Behavior</b>						
Injection risk	6.00 (6.436)	6.51 (6.694)	4.07 (5.792)	3.04 (4.352)	3.73 (6.868)	2.17 (3.881)
Sexual risk	4.26 (2.871)	5.00 (3.670)	3.69 (3.070)	4.31 (3.320)	3.055 (2.683)	3.195 (2.739)

\*ASI indicates Addiction Severity Index; AIDS, acquired immunodeficiency syndrome; M180, 180-day methadone-assisted detoxification; and MMT, methadone maintenance treatment. Enrollment N ranges from 86 to 88 for M180 and from 86 to 91 for MMT; 6-month N ranges from 54 to 60 for M180 and from 68 to 77 for MMT.

of differences between group and cocaine use given the missing assessment data, we reestimated the statistical model by setting the missing assessments to cocaine-positive use under 3 assumptions: positive enrollment cocaine test, more than half of assessments cocaine-positive, and any assessment cocaine-positive. Under all 3 assumptions, the difference between the groups was no longer significant, suggesting that the difference initially observed resulted from the higher probability of cocaine users dropping out of M180 than MMT. At each assessment, only 30% to 50% of participants assessed in either group were abstinent from cocaine.

#### Alcohol Use

The average ASI alcohol use composite score was low. On a scale from 0 to 1, with 1 the most problematic, mean scores were 0.11 or less at all assessments. There were no significant effects.

#### COMMENT

Methadone maintenance was found to increase retention and be more effective in decreasing heroin use than M180. Methadone maintenance treatment resulted in a lower level of drug-use HIV risk behavior and lower ASI legal composite scores during the second 6 months of the assessment period, when provision of methadone to M180 participants had ended. The ASI psychiatric, family, employment, and alcohol use composite scores and the RAB HIV-related sex behavior subscale score were not affected. Heroin and cocaine use rates were high in both groups over the entire 12-month period. There was evidence that participants using cocaine were more likely to drop out of M180 than MMT.

The rate of continued use of heroin in both groups is of concern. Methadone dosages were adequate by current practice standards. Dosages could reach 100 mg/d if warranted and averaged well over 80 mg/d. Too low a methadone dose, therefore, does not appear to be the reason for the failure of either treatment to markedly curtail

heroin use. Persistent use may reflect the participants' goals when they entered treatment—only 50% of the sample reported to us that they had a goal of total abstinence from illicit opioids.

The dropout rate from M180 was high throughout the course of the study. This may reflect more stringent requirements about attendance at psychosocial treatment than in the MMT group. An acceleration in dropout occurred at around 120 days, the point at which methadone dosage began to be decreased in this group.

The M180 group received psychosocial treatment for continued cocaine use; nevertheless, this group failed to suppress cocaine use rates. Psychosocial treatments have been shown to be effective in reducing cocaine use.<sup>23,24</sup> However, successful treatments were manualized and adapted from psychotherapeutic interventions, rather than the generic drug counseling provided by drug counselors in the present study.

Methadone maintenance treatment was more successful in retaining cocaine users in the treatment system than M180; however, it did not appear to affect the level of cocaine use because the 2 groups did not differ under several reasonable assumptions about cocaine use in participants with missing data.

Neither treatment had a marked effect on psychosocial functioning. It may be that the psychosocial services provided were inappropriate. For example, while most patients were marginally employed, no vocational rehabilitation services were available.

This study has implications for the treatment of opioid dependence. First, improvement is needed. That 50% of participants used an illicit opioid at least once a month is not encouraging. Given that methadone doses were adequate, failure may rest in the realm of psychosocial treatment. Neither program in this study provided extensive legal, employment, family, or psychiatric services. Participants showed little change in these areas. A cost-effectiveness study of the benefits of adding these services to methadone treatment is needed. Second, cocaine use remains a problem in

methadone maintenance programs. While a pharmacological treatment for cocaine dependence has not emerged, there is considerable evidence that cocaine use is responsive to a variety of psychological interventions, including group drug counseling,<sup>25</sup> group-administered cognitive behavior therapy,<sup>23</sup> individual relapse prevention interventions,<sup>26</sup> and contingency management.<sup>27</sup> Such specific, promising interventions need to be integrated into methadone treatment programs for cocaine users.

The generalizability of the results in the current study is limited in that the study represents only 1 clinical trial. The participants were a small subset of those who originally contacted the project and may differ from other methadone maintenance patients in unknown ways. However, the current study does not provide support for diverting resources from methadone maintenance to long-term detoxification, no matter how ideologically attractive the notion of a time-limited treatment for opioid abusers is.

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My task which I am trying to achieve is by the power of the written word, to make you hear, to make you feel—it is, before all, to make you see. That—and no more, and it is everything.

—Joseph Conrad (1857-1924)

# An Experimental Evaluation of Residential and Nonresidential Treatment for Dually Diagnosed Homeless Adults

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**SUMMARY.** Homeless adults with both a serious mental illness and substance dependence (N = 276) were randomly assigned to: (1) a social model residential program providing integrated mental health and substance abuse treatment; (2) a community-based nonresidential program using the same social model approach; or (3) a control

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group receiving no intervention but free to access other community services. Interventions were designed to provide 3 months of intensive treatment, followed by 3 months of nonresidential maintenance. Subjects completed baseline interviews prior to randomization and reinterviews 3, 6, and 9 months later. Results showed that, while substance use, mental health, and housing outcomes improved from baseline, subjects assigned to treatment conditions differed little from control subjects. Examination of the relationship between length of treatment exposure and outcomes suggested that residential treatment had positive effects on outcomes at 3 months, but that these effects were eroded by 6 months. [Article copies available from *The Haworth Document Delivery Service: 1-800-342-9678.*]

### INTRODUCTION

Following the movement in the 1960s and '70s to deinstitutionalize seriously mentally ill patients from long-term state hospital care, and in concert with the growth of the homeless population in the '80s and '90s, a new population of dually diagnosed individuals—those with both serious mental illness and substance dependence—has increasingly concerned providers in both mental health and substance abuse treatment settings. The literature indicates that these dually diagnosed individuals are at high risk of becoming homeless or relying on marginal housing arrangements.<sup>1-6</sup> Indeed, studies of homeless populations suggest that about 1 in 5 homeless adults have dual diagnoses.<sup>7-10</sup>

This new population poses difficult challenges for already strained public treatment and social welfare systems. Public mental health and substance abuse treatment have historically been delivered through separate funding streams and institutional settings, and the dually diagnosed present a clinical picture that exceeds the expertise and signals a poor prognosis in either of these separate systems.<sup>3,8,11-14</sup> While coordinating care across the two systems is theoretically possible, in practice differing treatment philosophies and barriers to clients presented by fragmented care have deterred the development of viable linkages between systems to better serve the needs of the dually diagnosed.<sup>13,15</sup> Treatment success for many dually diagnosed individuals may also be impeded by overarching needs for basic necessities such as stable housing, food, and clothing.

Such gaps in care for the dually diagnosed have stimulated the development of a number of pilot and demonstration treatment programs over the past several years. These have in common an integrated approach for treating the dually diagnosed that combines elements of traditional mental health care and substance abuse rehabilitation.<sup>12,16-22</sup> While these programs vary in their conceptual orientations, settings, service components, and intensi-

ty, most attempt to strike a balance between the typically nurturant and supportive approaches characterizing community-based treatment for the seriously mentally ill, and the more demanding and confrontational approach characterizing substance abuse therapeutic communities. Drug-free goals are modified to encourage appropriate use of psychotherapeutic medications. The few programs described in the literature that include a focus on persons who are both dually diagnosed and homeless have also emphasized the importance of assertive case management to assist clients in obtaining housing, income assistance, primary health care, and other needed social or educational services.

Although these emerging models of integrated treatment for dually diagnosed individuals are promising, the evaluation of such interventions to date has been greatly limited by small sample sizes, serious sample attrition, limited follow-up periods, and narrowly defined outcomes. For example, studies by Kofoed, Kania, Walsh, et al.,<sup>16</sup> Hellerstein and Meehan,<sup>17</sup> Ries and Ellingson,<sup>23</sup> Drake, McHugo, and Noordsy,<sup>22</sup> and Hoffman, DiRito, and McGill<sup>20</sup> all presented outcomes of treatment for dually diagnosed samples using post-assessment only designs, and none had sample sizes greater than 32. The most rigorous test of a treatment program for the dually diagnosed to date has recently been reported by Blankertz and Cnaan<sup>21</sup> who studied 84 subjects using a quasi-experimental design in which two treatment programs for the dually diagnosed were compared. The main outcomes that have been examined in these studies are retention in the program<sup>16,17,21</sup> or abstinence rates during or shortly following the treatment.<sup>20,22</sup> No studies in the literature to date have included an experimental design that randomizes subjects to conditions.

This report presents treatment outcome results of a research demonstration project focusing on dually diagnosed and homeless adults. The demonstration interventions were based on a social model recovery approach which combined elements of substance abuse recovery and mental illness management. The goal of this social model approach is to assist clients in developing an independent life in the community through abstinence from alcohol and street drugs and by enhancing their social and vocational abilities. The program philosophy is that this goal is best achieved in small, structured, therapeutic environments in which clients learn by interaction with one another, with staff, and with the surrounding community. Principles of this philosophy are that: (1) abstinence is prerequisite for effective program participation; (2) a program environment that is designed and maintained to dignify both clients and staff is an essential aspect of the treatment process; (3) a structured schedule of activities is needed to develop new behavior patterns; (4) a well-trained staff should provide compre-

hensive therapeutic services; (5) a strong, long-term case management effort is essential; (6) participation in self-help groups is an essential and ongoing aspect of recovery; and (7) each client should be respected and valued as someone with an important contribution to make to the community and society as a whole.

### **DEMONSTRATION INTERVENTIONS**

To evaluate this intervention approach, we studied 276 homeless and dually diagnosed individuals who were randomly assigned to one of three conditions; a social model residential treatment program; a nonresidential program using the same social model approach; and a control group.

The residential treatment program was in existence prior to the initiation of the research demonstration. As part of this demonstration, treatment slots were made available to research participants without the usual 2- to 3-month waiting period that had effectively served as a barrier to homeless persons. The nonresidential program was newly implemented as part of the demonstration, and was modeled after the residential program, so that the programs operated under the same philosophy and were designed to have many common service elements. Common activities included: (1) curriculum-based groups focused on substance abuse and mental health education and rehabilitation; (2) 12-step programs including participation in community-based AA or NA meetings; (3) process-oriented groups to facilitate discussion of issues of importance to the clients; (4) individual counseling and case-management; (5) psychiatric consultation and ongoing medications management; and (6) general community activities including doing chores, helping with meal preparation, participating in sports and recreational activities, and personal time.

While the residential program was by definition a 24 hour, 7 day per week program, the nonresidential program operated in the afternoon and evening (1:00 pm to 9:00 pm) five days a week. Differences between the programs in the schedule of activities, emphasis on case management, expectations, and program rules were necessary to adapt the residential model to a nonresidential setting. For example, abstinence from drugs or alcohol was a requirement for remaining in the residential community and a single infraction confirmed with drug testing resulted in expulsion from the program. In the nonresidential setting, clients were not allowed to attend the program on any day that they were discernibly intoxicated on alcohol or drugs, but staff continued to work with these clients to engage them in the program and encourage their sobriety, irrespective of number of relapses. In addition, nonresidential clients received much more case man-



agement assistance from program staff than did residential clients, given their often pressing needs for shelter, meals, transportation, and income assistance.

Both interventions were designed to consist of a 3-month intensive phase. Successful completion of this first phase was followed by another period of 3 months during which both residential and nonresidential graduates were encouraged to continue to participate in program activities in the nonresidential setting. After the second three-month period (Phase 2), those who wished could continue to engage in program activities of their choosing. Upon completion of Phase 1, clients were invited to reside in a lightly supervised sober-living residence sponsored by the program and operated along an Oxford House model. Residents of the sober-living houses could remain as long as they wished as long as they were able to pay their share of the rent, remain sober, and get along reasonably well with other residents. Those who preferred other living arrangements were assisted in locating permanent housing. Further descriptions of the intervention can be found in McGlynn et al.<sup>24</sup> and Stecher et al.<sup>25</sup>

Those who were assigned to the control group received no special intervention, but were free to access other available community services (such as homeless shelters, a mental health clinic, a day socialization center, and AA groups). While both a public mental health clinic and a nonprofit substance abuse treatment facility serving homeless individuals were located in the community, clients who were dually diagnosed were known to be shunned by these programs.

## RESEARCH METHODS

### *Community Setting and Research Participants*

The study focused on homeless persons in the Westside area of Los Angeles County, a predominantly residential urban area that includes the two beach communities of Santa Monica and Venice, and contains a large concentration of homeless persons. While several agencies provide food, shelter and a variety of social services to homeless persons in this community, the cost of housing is generally high, access to moderately priced housing is intensely competitive, and there is substantial community resistance to the development of facilities that serve the homeless. As a result, transitional and low-income housing is very scarce, and emergency shelter facilities are able to house only about one quarter of the homeless (about 15% of men and 45% of women) on any given night.<sup>26</sup> Prior to this research demonstration, there were no programs on the Westside that were

specifically designed to address the problems and needs of homeless and dually diagnosed individuals.

Participants were recruited from existing community agencies serving the homeless, including shelters, day centers, a substance abuse program, and a mental health clinic. Potential participants were either individually referred from an agency to research staff, or research staff visited agencies and directly approached their clients. Those who agreed to be interviewed by research staff participated in a brief screening interview which established whether or not participants met criteria for homelessness (either literally homeless or lived in two or more dependent housing situations in the past 6 months), and screened for symptoms of serious mental illness and a history of problems with alcohol or drugs. Those who met criteria at this stage were asked to participate in a structured diagnostic interview administered by nonclinician interviewers (the Diagnostic Interview Schedule, Version III-R) to confirm diagnoses. Those meeting lifetime DSM III-R criteria for schizophrenia or major affective disorder, and also criteria for substance dependence (with some substance abuse or dependence problems in the past year) were eligible for the study. Of those who participated in the initial screening interview (N = 1112), 64% met initial eligibility criteria. Among screener eligibles (N = 717), 81% completed the diagnostic interview. Of those completing the diagnostic interview (N = 583), 83% (N = 484) were fully eligible for study participation.

Among persons determined to be eligible, 57% (N = 276) agreed to participate in the study and be randomly assigned to conditions. After completing baseline interviews, these subjects were randomly assigned to nonresidential treatment (N = 144), residential treatment (N = 67), or the control group (N = 65). Probability of assignment to the nonresidential group was set at twice that of the other groups because we expected a higher degree of variability in exposure to treatment for those assigned to this intervention, and would therefore need a relatively larger sample size to detect a treatment effect. Random assignment was made within two blocking variables, gender and primary type of mental disorder (schizophrenia versus affective). Study participants were asked to complete follow-up interviews at 3 months, 6 months, and 9 months following their baseline interviews. The 3-month interview occurred around the time of completing treatment Phase 1 (among those who stayed in treatment). Participants were sought for follow-up interviews during a 2-month window of time spanning their scheduled follow-up date whether or not they were in treatment. Those who were not found for one follow-up interview were again sought for subsequent interviews. Participants were paid \$2 for completing the initial screening interview, and \$10 for completing each of

the diagnostic interview, baseline interview, and follow-up interviews. Those who called in to schedule an appointment for their follow-up interviews (using a toll-free number) were given an additional \$2.

### *Measures*

The evaluation of the treatment interventions focused on the three major outcome domains: substance use, severity of mental illness symptoms, and housing status. Questions regarding substance use asked about frequency (and in the case of alcohol, quantity) of use of different categories of drugs in the past 30 days. Four measures of substance use were constructed: (1) number of days consumed any alcohol in the past 30; (2) number of days used any illicit drugs in the past 30; (3) a quantity index reflecting 3 levels of alcohol use in the past 30 days: abstinence, low quantity consumption (less than 3 oz. absolute alcohol or 5 drinks on any day), and high quantity consumption (at least 3 oz. absolute alcohol or 5 drinks on at least one day), based on a measure developed by Pollich and colleagues,<sup>27</sup> and (4) a drug use index weighting frequency of use by the severity of the drug used, as suggested by Phin,<sup>28</sup> and modified by Bray and colleagues.<sup>29</sup> Mental illness symptom questions referred to the past 7 days, and covered dimensions of depression, anxiety, psychoticism, anger/hostility, taken from the SCL-90,<sup>30-32</sup> with mania and self-esteem scales included from the Psychiatric Epidemiologic Research Interview (PERI).<sup>33</sup> Internal reliability of each of these scales was high (Cronbach's alphas ranged from .60 for mania to .82 for self-esteem). The depression and anxiety scales were combined into one because of lack of discriminant validity between the separate scales, and the resulting scales adequately reflect discrete dimensions, with interscale correlations ranging from 0 to .5. To assess recent housing and homelessness patterns, the interview asked subjects to provide a history of their living arrangements over the past 60 days, which were classified into the following categories: on the streets (including abandoned buildings, parked cars, bus depots, parks); independent housing (own house, apartment, room, boarding house, group home); and dependent housing (emergency shelters, health and correctional facilities, doubled up with family or friends). The housing status measures we used in analyses of outcomes were the percentage of nights in the past 60 that respondents spent on streets and the percentage of nights spent in independent housing, with the percentage of nights spent in dependent housing as the omitted category.

Prognostic and history variables measured at baseline that were considered as covariates in analyses of outcomes included demographic characteristics (gender, age, race, marital status, veteran status, educational level),

primary thought versus mood disorder, number of symptoms of alcohol dependence in the past year, number of symptoms of drug disorder in the past year, presence of antisocial personality, number of years homeless, satisfaction with physical health, prior hospitalization for psychiatric problems, and prior substance abuse treatment. In addition, other history variables were considered as covariates for specific outcome domains. For substance use outcomes, we examined the number of years subjects had regularly used alcohol to the point of getting high or drunk, number of years they had used any other drugs regularly, ever had alcohol DTs, ever overdosed on drugs (all taken from The Addiction Severity Index,<sup>34</sup> and the Alcohol Dependence Scale<sup>35</sup>). For housing outcomes, we included age at which subjects first became homeless. For mental health symptom outcomes, we considered age of first major symptom of schizophrenia or affective disorder, and the presence of episodes of schizophrenia, major depression, and mania in the past year.

The study also assessed out-of-program treatment received by both the experimental treatment and control groups at baseline and in each follow-up period. Measures used in analyses to control for out-of-program treatment exposure included: (1) the log of days of attendance at AA (12-step) meetings in the past 30 days (not counted if the client was active in the experimental treatment interventions during the past month, since attendance at AA meetings was a component of the intervention); (2) any use of prescribed psychotherapeutic medications in the past 30 days; (3) any inpatient or outpatient treatment for a mental health problem in the past 30 days; and (4) any formal treatment (residential or nonresidential) for a substance abuse problem in the past 30 days.

### *Analysis*

Two sets of analyses were conducted to examine the effects of treatment on outcomes, testing whether: (1) outcomes differ across subjects assigned to nonresidential vs. residential treatment groups; and (2) outcomes differ between those assigned to treatment vs. control groups (with residential and nonresidential conditions combined). General linear regression models were used to examine treatment effects, with the difference score between baseline and follow-up outcome measures constituting the dependent variable, and treatment assignment as the independent variable. Because we did not adjust the variances for our stratified random design effect that resulted from blocking prior to randomization, our regression coefficient tests are conservative. Separate analyses were performed for each baseline to follow-up difference score (i.e., baseline to 3 months, baseline to 6 months, baseline to 9 months) and for each of the 11 outcome

measures. Difference scores were constructed so that, across all outcome measures, a positive score indicated improvement in functioning, while a negative score indicated decline in functioning. Unadjusted regression models included only treatment assignment as a predictor of outcome difference scores, while adjusted regression models included both treatment assignment and relevant baseline covariates as predictors. Given our relatively small sample size, a parsimonious covariate selection procedure was required to deal with the large number of potential covariates. Relevant covariates to include in the models were thus selected using backwards stepwise linear regression to identify those significantly associated with the outcome domain irrespective of group assignment. The stepwise selection procedure was used within each outcome domain (such as substance use), and covariates which were consistently significant for outcomes within this domain were selected. The set of selected covariates was therefore identical for each outcome within a domain but differed across domains.

A final set of regression analyses tested whether level of treatment exposure predicted outcomes at each of the follow-up periods, with exposure measured as the log number of days subjects participated in the treatment program. Because exposure to treatment was self-selected, each of these models included baseline covariates to control as much as possible for self-selection biases. Indicators of out-of-program exposure to substance use and mental health services were then added to the models to control for potential contamination of the treatment versus control group comparisons.

## RESULTS

### *Study Sample and Attrition*

The characteristics of the 276 persons who completed a baseline interview and were randomly assigned to one of the three study conditions are shown in Table 1. The large majority were unmarried males in their 30s and 40s with at least a high school degree. The sample was nearly equal in the distribution of primary schizophrenia versus major affective disorder. Both drug and alcohol dependence were highly prevalent, with many individuals reporting problems across multiple substances. In the past month, 53% of the sample had used cocaine, 47% used marijuana, 24% used sedatives, 9% used opiates, 8% used amphetamines, 6% used hallucinogens, and 3% used barbiturates and inhalants. While the three study groups were closely comparable at baseline in most characteristics that

TABLE 1. Characteristics of Sample by Treatment Group Assignment.

	Nonresidential Treatment	Residential Treatment	Controls	Total
	(N = 144)	(N = 67)	(N = 65)	(N = 276)
% Male	83	81	89	84
Mean Age (in years)	37	36	37	37
Race				
% White	56	57	65	58
% Black	30	31	21	28
% Other	14	12	14	14
Marital Status**				
% Currently married	5	15	0	6
% Previously married	47	46	40	45
% Never married	48	39	60	49
% Veteran	34	33	40	35
Education				
% < High School	29	27	25	28
% High School	29	39	41	34
% Some College	42	34	34	38
Mean Years Homeless	4.9	3.7	5.1	4.7
Mean no. of nights slept on street of past 60	49	49	51	49
Mental Disorder				
% Schizophrenia only	7	6	8	7
% Major affective only	56	60	48	55
% Both	37	34	44	38
Alcohol Disorder in past year	79	76	80	79
Mean no. symptoms	3.8	3.4	3.8	3.7
Drug Disorder in past year	74	72	69	72
Mean no. symptoms	3.9	4.2	3.5	3.9

\*\*Significant difference among groups at  $p < .01$

were examined, there was a significant difference across groups in their marital status. We note that only this 1 significant difference was found among 15 variables tested that included 4 not shown in Table 1: presence of antisocial personality, satisfaction with physical health status, prior hospitalizations for psychiatric problems, and prior treatment for substance abuse problems. This high degree of similarity across groups provides assurance that randomization procedures were appropriately implemented and resulted in comparable groups.

Rates of completed follow-up interviews among the 276 study participants were 79% for the 3-month follow-up, 76% for the 6-month follow-up, 70% for the 9-month follow-up, and 58% completed all three follow-ups. Follow-up completion rates were not different across the three treatment conditions, except at the 9-month follow-up, where the completion rate among those assigned to the control group (57%) was significantly lower than among those assigned to nonresidential treatment (76%).

While this is a relatively low level of attrition for a longitudinal study of homeless persons, we were concerned that it had the potential to introduce bias into the findings, if factors associated with study attrition differed across groups. To determine whether differential attrition was a concern, we tested whether the three treatment groups remained comparable at each of the follow-up periods with respect to the fifteen baseline variables described above. These analyses showed that the three study groups differed in satisfaction with physical health status at the three-month follow-up; the residential and nonresidential groups differed in marital status at six months; and the control group differed from both the residential and nonresidential groups in marital status at nine months. Considering that multiple tests were conducted, this relatively small number of significant results suggests that the study groups were largely comparable at each of the follow-up timepoints.

#### *Nonresidential and Residential Treatment Outcomes*

No significant differences were found between nonresidential and residential treatment groups at any of the three follow-up periods for any of the outcomes examined, with the exception of time spent in independent housing at the 3-month follow-up (see Table 2). Those assigned to nonresidential treatment were more likely to have increased the amount of time they spent in independent housing at 3 months following baseline, relative to those in residential treatment. This finding is expected because the 3-month follow-up was scheduled immediately after the first phase of treatment completion, and subjects in residential treatment were by definition not independently housed. While Table 2 provides adjusted mean differ-

TABLE 2. Adjusted differences in substance use, mental health, and housing patterns over time by residential versus nonresidential treatment assignment.

Group Assignment	Mean at Baseline <sup>†</sup>		Mean differences from Baseline to Follow-up Assessment <sup>‡</sup>					
	Nonresidential (N = 144)	Residential (N = 67)	3-Month Follow-up (N = 114)		6-Month Follow-up (N = 114)		9-Month Follow-up (N = 110)	
			Nonresidential (N = 57)	Residential (N = 57)	Nonresidential (N = 49)	Residential (N = 49)	Nonresidential (N = 45)	Residential (N = 45)
<b>Substance Use in Past 30 days</b>								
Days used alcohol	11.4	11.5	4.5	6.5	3.8	3.8	5.6	4.6
Level alcohol use	1.4	1.5	0.4	0.7	0.3	0.4	0.4	0.3
Days used drugs	9.8	8.3	3.1	5.2	2.6	1.9	3.8	3.4
Severity drug use	4.2	3.7	1.2	1.6	0.8	0.8	1.9	1.5
<b>Current Mental Health Symptoms</b>								
Depression and anxiety	52	55	7.6	8.9	9.2	10.0	9.3	13.2
Psychotic symptoms	25	25	3.0	0.4	3.4	6.1	5.6	4.0
Anger and hostility	27	28	-0.6	-0.9	-2.9	2.4	-0.8	-1.4
Mania	32	37	-0.5	3.7	0.0	0.6	0.5	2.6
Self esteem	47	50	8.5	4.5	9.0	9.5	5.6	4.0
<b>Housing Status in Past 60 days</b>								
% time on streets	52	48	20	25	27	27	21	19
% time in independent housing	18	16	15*	-1	19	33	18	14

<sup>†</sup> Range for "days used alcohol" and "days used drugs" was 0 to 30 days. "Level alcohol use" ranged from 0 (none) to heavy (2) while "severity drug use" was scored from 0 to 75. Measures of mental health symptoms and housing status all ranged from 0 to 100.

<sup>‡</sup> Underlined differences are significantly different from zero (no change from baseline) at p < .05. Positive numbers indicate improvement in outcome from baseline to follow-up (less substance use, better mental health, less time homeless on streets, more time independently housed); while negative numbers indicate poorer outcome from baseline to follow-up.

\*Difference between residential and nonresidential treatment group is significant at p < .05.



ences in scores between baseline and follow-up measures, controlling for relevant baseline covariates, results were similar for analyses of unadjusted means. Table 2 also shows that both nonresidential and residential treatment groups reported significant improvement in many outcomes from baseline to follow-up assessments, especially for measures of substance use, symptoms of depression/anxiety, self-esteem, and indicators of housing status. No improvement was evidenced in measures of psychotic symptoms, mania, or anger/hostility.

We then combined residential and nonresidential treatment assignment groups and compared the outcomes of those assigned to treatment to those assigned to the no-treatment control group. In spite of significant improvements between baseline and follow-up assessments across most outcome measures in the treatment groups, there were few significant differences between the treatment and control groups in outcomes (see Table 3). The only outcome measure for which treatment groups displayed a significantly greater improvement than the control group was days of alcohol use at the 3-month follow-up. For many outcomes, the control group, like the treatment groups, showed improvements from baseline to follow-up assessments. Unadjusted mean comparisons gave similar results to the adjusted mean comparisons shown here.

#### *Exposure to Treatment and Its Relationship to Outcomes*

Although both the nonresidential and residential programs made efforts to engage all subjects assigned to treatment, 40% of those assigned to either program never attended, with no difference in nonattendance rates between the nonresidential and residential programs. Among those who attended, retention was higher in the residential than the nonresidential program. In the residential program, 49% of those assigned stayed in the program for at least two weeks, and 24% successfully completed Phase 1. In the nonresidential program, only 36% of those assigned attended as much as 2 weeks of the program over the study period (10 program days), and only 8% successfully completed Phase 1.

Results of analyses examining changes in outcomes between baseline and follow-up as a function of log days of residential and nonresidential program exposure, controlling for treatment group assignment and relevant baseline covariates, are shown in Table 4. Significant treatment exposure effects were found for residential treatment across substance use and housing outcomes at the 3-month follow-up, indicating that longer retention in residential treatment was associated with better outcomes. However, these positive effects of residential treatment exposure found at 3 months were not maintained at the 6- and 9-month follow-ups, with the exception of

TABLE 3. Adjusted difference in substance use, mental health symptoms, and housing patterns over time by treatment versus control group assignment.

Group Assignment	Mean at Baseline <sup>1</sup>		Mean differences from Baseline to Follow-up Assessment <sup>2</sup>					
	Treatment (N = 211)	Control (N = 65)	3-Month Follow-up		6-Month Follow-up		9-Month Follow-up	
			Treatment (N = 171)	Control (N = 47)	Treatment (N = 163)	Control (N = 46)	Treatment (N = 155)	Control (N = 37)
<b>Substance Use in Past 30 days</b>								
Days used alcohol	11.4	12.3	5.2 **	0.6	3.5	2.8	5.3	5.4
Level alcohol use	1.5	1.6	0.5	0.2	0.3	0.5	0.4	0.6
Days used drugs	9.3	4.5	3.8	1.4	2.4	3.8	3.8	3.8
Severity drug use	4.1	4.5	1.3	0.7	0.8 *	2.2	1.8	2.5
<b>Current Mental Health Symptoms</b>								
Depression and anxiety	53	53	7.9	7.5	7.3	19.4	10.8	15.5
Psychotic symptoms	25	27	2.1	3.9	4.2	4.9	5.2	7.0
Anger and hostility	27	27	-0.1	-7.8	-1.3	2.8	-1.0	2.5
Mania	34	32	0.9	0.2	0.2	2.5	1.1	6.2
Self-esteem	49	47	7.2	4.4	8.5	7.1	6.2	2.8
<b>Housing Status in Past 60 days</b>								
% time on streets	51	53	22	22	27	22	21	26
% time in independent housing	17	14	10	11	23	14	17	22

<sup>1</sup> Range for "days used alcohol" and "days used drugs" was 0 to 30 days. "Level alcohol use" ranged from 0 (none) to heavy (2) while "severity drug use" was scored from 0 to 75. Measures of mental health symptoms and housing status all ranged from 0 to 100.

<sup>2</sup> Underlined differences are significantly different from zero (no change from baseline) at  $p < .05$ . Positive numbers indicate improvement in outcome from baseline to follow-up (less substance use, better mental health, less time homeless on streets, more time independently housed); while negative numbers indicate poorer outcome from baseline to follow-up.

\* Difference between treatment and control group is significant at  $p < .05$ .

\*\* Difference between treatment and control group is significant at  $p < .01$ .

TABLE 4. Relationship of treatment exposure to changes in substance use, mental health, and housing patterns.

Regression Coefficients for Significant Effects of Treatment Exposure on Differences in Outcomes Between Baseline and Follow-up Assessments <sup>1</sup>					
3-month Follow-up		6-month Follow-up		9-month Follow-up	
Non-res. days	Res. days	Non-res. days	Res. days	Non-res. days	Res. days
Substance Use in Past 30 Days					
	Days used alcohol		1.73	1.49	
	Level alcohol use		0.16		
	Days used drugs		1.70		
	Severity drug use				
Current Mental Health Symptoms					
	Depression and anxiety				
	Psychotic symptoms				
	Anger and hostility				
	Mania				
	Self-esteem				
Housing Status in Past 60 days					
	% time on streets		0.03		
	% time in independent housing			0.08	

<sup>1</sup> Regression coefficients are shown for treatment exposure effects that were significant predictors of outcomes, controlling for treatment assignment and baseline covariates. All other treatment exposure coefficients were nonsignificant.

improvements in independent housing at 6 months. Days of nonresidential treatment participation had less discernible effect on outcomes, showing only one significant association with days of alcohol use at 6 months, and no significant association with outcomes at 3 or 9 months.

When indicators of out-of-program treatment were added to these regression models to control for possible contamination of the experimental treatment effect through use of other substance abuse and mental health related services (see Table 5), further significant effects of exposure to nonresidential and residential treatment emerged. Exposure to nonresidential treatment, in addition to predicting improved substance use outcomes at 6 months, was also associated with improvements in depression/anxiety

TABLE 5. Relationship of Treatment Exposure and Out-of-Program Treatment to Changes in Substance Use, Mental Health, and Housing Patterns.

	Regression Coefficients for Significant Treatment Exposure and Out-of-Program Treatment on Differences in Outcomes Between Baseline and Follow-Up Assessments <sup>1</sup>													
	3-month Follow-Up				6-month Follow-Up				9-month Follow-Up					
	Study Intervention		Out-of-Program Treatment*		Study Intervention		Out-of-Program Treatment*		Study Intervention		Out-of-Program Treatment*			
	Non-res. days	Res. days	AA	Meds	MH TX	SA TX	Non-res. days	Res. days	AA	Meds	MH TX	SA TX		
Substance Use in Past 30 days														
Days used alcohol	1.97	1.68							2.14					
Level alcohol use			0.17				0.13			0.17				
Days used drugs	1.96	1.60												
Severely drug use												0.62		
Current Mental Health Symptoms														
Depression and anxiety	3.33	4.09	3.52											
Psychotic symptoms														
												-13.0	8.09	-11.4

Anger and hostility	4.01	5.20
Mania		
Self-esteem	3.77	-10.3
Housing Status in Past 60 days		
% time on streets	0.08	
% time in independent housing		

-8.22

Regression coefficients are shown for treatment exposure effects that were predictors of outcomes, controlling for treatment assignment and baseline covariates. All other treatment exposure coefficients were nonsignificant. "AA" is log of days attended 12-step meetings in past 30. "Meds" is any use of prescribed psychotherapeutic medications in past 30 days. "MH TX" is any inpatient or outpatient mental health treatment in the past 30 days. "SA TX" is any formal treatment (residential or non-residential) for a substance problem in the past 30 days.

at 3 months. Exposure to residential treatment, in addition to having positive effects on substance use and housing outcomes at 3 months, was also associated with improvements in two measures of mental health status at 3 months (depression/anxiety, anger/hostility). The effect of nonresidential treatment on housing status at 6 months, however, was reduced to nonsignificance.

These analyses also showed that indicators of out-of-program treatment were sometimes significantly associated with outcomes. Of particular interest is the association of attendance at AA meetings with improvements in substance use outcomes at all three follow-up periods, and also with improvements in mental health symptoms (depression/anxiety, anger/hostility, and self-esteem) at the 3-month follow-up. Use of psychotherapeutic medications was generally not associated with outcomes, except for a negative association with psychotic symptoms at 3 months, perhaps reflecting a reverse causal association (that is, those with increasing levels of psychotic symptoms being more likely to get and use medications). Out-of-program mental health treatment was associated with some positive outcomes (improvements in psychotic symptoms at 3 months and substance use at 9 months), but was also related to lower self-esteem at 3 and 9 months. Out-of-program substance abuse treatment had no discernible association with outcomes, except for an association with increased psychotic symptoms at 3 months that is not readily interpretable.

## DISCUSSION

The most rigorous test of the effectiveness of a treatment intervention is the experimental design, in which subjects are randomly assigned to treatment and control groups, and the outcomes of all persons assigned are compared between groups. Using this evaluation standard, we found little discernible effect of intensive integrated treatment on substance use, mental health, or housing outcomes among dually diagnosed and homeless adults. On only one measure, frequency of alcohol use, did the treatment groups show more improvement than the control group. And this positive effect, while significant at the end of the 3-month intensive phase of treatment, was not detectable at the 6- or 9-month follow-ups. Because our sample sizes were adequate for detecting medium-sized effects (0.5), the absence of detectable treatment effects cannot be attributed to insufficient statistical power.

Previous studies of integrated treatment interventions for dually diagnosed individuals have reported positive outcomes with much smaller sample sizes, but have not employed experimental designs, and often excluded

from analysis persons who dropped out of treatment early. Both of these design weaknesses are likely to have biased results towards finding positive effects of treatment. In the case of nonexperimental pre- and post-treatment comparisons, simple regression to the mean could explain improvements from before to after treatment, particularly if subjects are selected into treatment during a period of acute problems with substance abuse and/or mental illness. Such regression to the mean could explain why, in the present study, the control as well as the treatment groups showed improvements in many outcomes from baseline to follow-up assessments. Another possible explanation for improvements in the control as well as the treatment groups is that the control group was "contaminated" by its exposure to other types of mental health, substance abuse, and homeless services. This explanation suggests that the improvements in the treatment groups from baseline to follow-up assessments are truly positive outcomes of treatment rather than regressions to a mean level of functioning, but that the control group also improved as a result of the variety of services that it received and therefore masked the differences between the treatment and control conditions. Perhaps those assigned to the control conditions were nonetheless stimulated by the research protocol to seek help for their substance abuse and mental health problems. In analyses designed to partial out the contaminating effects of use of services received outside of the experimental treatment interventions, significant treatment exposure effects were found, but these were largely restricted to a positive impact of residential treatment on substance use and mental health at the 3-month follow-up (occurring at the end of the intensive treatment period). These results suggest that residential treatment effects were real, but short-lived, and that regression to the mean may explain apparent pre-post improvements in outcomes over the longer period of evaluation.

While it is common in treatment evaluation studies to exclude from analysis subjects who drop out of treatment early, this practice can seriously bias results if, as many clinicians believe, those clients who are more likely to have poor outcomes anyway are also most likely to drop out of treatment and those who have a good prognosis most likely to stay in. For this reason, we included in our analyses all persons who agreed to be assigned to either a treatment or control group. Conceptually, one can think of this as a test of the effectiveness of the programs' "intention" to provide treatment to a targeted group of individuals. This is the most rigorous and appropriate test of treatment because it avoids biases introduced by selective treatment retention. At the same time, it raises concerns that high rates of early drop-out from both treatment programs may have diluted real treatment effects among those who had more exposure to the interventions.

When we analyzed the relationship of days of treatment exposure to outcomes, a consistent effect of residential treatment on improved outcomes at 3 months did, in fact, emerge. Because we had comprehensively assessed variables that might be expected to predict outcomes at baseline, and included these as covariates in our models, we can cautiously assert that exposure to a 3-month intensive social model residential treatment intervention improved outcomes over what would have been expected in this dually diagnosed and homeless population, but only for a short period of time.

One issue that merits special attention with this population is the limited extent to which newly emerging programs specifically designed for the dually diagnosed appear to have been successful in engaging them in sustained treatment efforts. Among studies reporting any information about treatment drop-outs, most report high rates of early program attrition: 66% dropped out of a once-a-week VA outpatient group within 2 months in Kofoed and colleagues' pilot study;<sup>16</sup> five out of ten clients dropped out of another weekly outpatient group within 1 year as reported by Hellerstein and Meehan;<sup>17</sup> Blankertz and Cnaan<sup>21</sup> give drop-out rates of 43% and 106% among homeless dually diagnosed clients within the first 2 months of a structured residence program and modified therapeutic community, respectively. Drop-out rates in the present demonstration were also high. Among those who attended at least once, drop-out rates in the first two weeks were 18% and 40% in the residential and nonresidential groups, respectively. If those who agreed to participate in the demonstration but never entered treatment are included, these early drop-out rates increase to 51% and 64%. While some treatment attrition is to be expected, particularly for programs demanding sobriety of substance abusers, the dually diagnosed seem particularly difficult to engage in treatment even when it is specially targeted to their comorbid disorders.

In hindsight, we speculate that engagement and retention of this population could have been improved by restructuring the intervention in two ways. First, an extended and low-demand first phase of entry into the program may have boosted participation. It is our impression that some individuals who were not quite "ready" to commit themselves to treatment at the time they entered the demonstration would over time have become involved given a more flexible and low-demand option for engaging. This idea has been articulated by others<sup>10,36</sup> as a model in which clients progress, or regress if necessary, through different phases of treatment, with engagement and persuasion as the first phases (for example, through mental health treatment settings where abstinence is a goal but not a requirement), followed by more active treatment and relapse prevention



(with higher expectations for abstinence and a focus on skills to maintain abstinence).

Second, we think that our treatment approach underestimated the primacy of housing and income needs in this population, and the difficulties involved in assisting clients with such needs even with intensive case management. This was particularly a problem for clients in the nonresidential program, who usually required immediate efforts to secure temporary shelter and apply for disability and/or welfare income assistance. Because housing of any type was difficult to access in this community (including emergency or transitional housing as well as permanent housing), program staff were often frustrated in their efforts. We believe that low-demand but highly supervised transitional housing linked to the nonresidential program would have increased its effectiveness in engaging and retaining clients. Expanded affordable permanent housing options for both residential and nonresidential clients upon completion of the initial intensive phase of treatment might have facilitated continued treatment involvement and gains in sobriety. Although a project-sponsored sober-living house and apartments were available, the financial feasibility of this option was dependent upon all residents contributing their share to the monthly rent, and upon fully occupied dwellings (2 residents per bedroom). The sober living homes failed to attract and maintain many treatment graduates because of their expense (only those who had qualified for and received SSI could afford the rent), the inability of some clients to live cooperatively and in close quarters with others, and the requirement that residents remain abstinent. In addition to the universal need, in our target population, for very low- or no-cost housing options, a range of housing environments in addition to sober-living homes such as single apartments, supervised community support residences or half-way houses, and moderately "wet" transitional housing would have better served the range of residential needs that existed.

Our experience has also led us to question the appropriateness of applying relatively short-term treatment models to the joint problems of serious mental illness and substance dependence. Serious mental illness is by definition the presence of a persistent and often lifelong disorder characterized by acute exacerbations and serious functional impairment. The natural course of substance addiction is also typically prolonged or chronic, characterized by multiple episodes of remittance and relapse among treated populations. Given this reality, it is perhaps not surprising that a relatively short-term intervention would have little detectable and lasting impact. What may be needed to stabilize and maximize the functioning of dually diagnosed individuals is a model of care that is very long-term and contin-

uous, such as that described by Drake, McHugo, and Noordsy<sup>22</sup> who report high rates of abstinence among 18 individuals who were treated continuously in an integrated dual diagnosis program over a period of four years. In this regard, an interesting finding from our study is that those subjects who attended AA meetings, beyond participation in the experimental treatment interventions, had better substance use outcomes over the course of the 9-month evaluation. This finding must be interpreted cautiously because it is possible to explain as an individual selection effect (that is, individuals who have better outcomes are more likely to attend AA meetings) and cannot conclusively be attributed to the efficacy of AA involvement. Nonetheless AA groups do have the advantage of providing a continuously available—even lifelong—source of support for this population, unlike formal treatment programs. While long-term support for sobriety may increase positive outcomes among the homeless dually diagnosed, we think it unlikely that any program, formal or self-help, is likely to produce long-lasting benefits unless issues of housing and income support are also resolved for this population.

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Special Population Outpatient Programs

Agency	Program Name	Modality	Target Population	Number of Static Slots	Cost Per Static Slot	Average Cost per Static Slot*	Annual General Fund Program Amount	Subtotal by Category
<b>Day Treatment - Youth and Families</b>								
Walden House	Adolescent Day Tx	Day Tx	Youth	8	\$ 17,893		\$ 143,147	
Morrisania	YORRES	Day Tx	Youth, C.J. Sp. Speaking	19	\$ 20,506		\$ 357,150	
Horizons	Day Tx	Day Tx	Youth	14	\$ 21,692		\$ 303,688	
Mission Council	Family Day Tx	Day Tx	Parents, Children	19	\$ 21,746	\$ 20,887	\$ 413,180	\$ 1,217,165
<b>Totals</b>				<b>60</b>				
<b>Outpatient - Women, Children/Youth, Mon-Lingual Speakers, Seniors, Hearing Impaired</b>								
Mission Council	Outpatient	Outpatient	Sp. Speaking	40	\$ 5,521		\$ 195,835	
Sage	Satellite Sexual Trauma Center	Outpatient	Adults	15	\$ 10,884		\$ 163,253	
YMCA Urban Svs	Balboa Teen Center	Outpatient	Women	5	\$ 14,534		\$ 3,233	
U.C Ctr Deafness	O/P Services for Deaf	Outpatient	Youth	3	\$ 16,833		\$ 50,500	
New Leaf	ODF	Outpatient	Hearing Impaired	16	\$ 28,965		\$ 384,453	
New Leaf	MSM Stim.	Outpatient	GLBT	8	\$ 31,769		\$ 254,150	
SFGH	Stonewall	Outpatient	MSM	7	\$ 22,162		\$ 155,136	
Walden House	Sister	Outpatient	Abusers	3	\$ 17,959		\$ 53,876	
Horizons	Outpatient	Outpatient	Women - C.J	16	\$ 16,955		\$ 248,670	
Curry Center	Home Visit/Counseling	Outpatient	Sp. Speaking	14	\$ 17,444		\$ 244,209	
BVHP	Youth Services	Outpatient	Senior Women	15	\$ 18,007		\$ 247,603	
Ohlhoff	Youth Outpatient	Outpatient	Youth	6	\$ 18,068		\$ 91,373	
Haight Ashbury	Bill Pone	Outpatient	Youth	5	\$ 19,177		\$ 95,884	
Iris Center	Children's Services	Outpatient	API, Somoans	6	\$ 21,147		\$ 126,880	
AAARS	Lee Woodward	Outpatient	Children	15	\$ 26,156		\$ 392,341	
Iris Center	Iris Project	Outpatient	Women	20	\$ 30,687		\$ 267,603	
<b>Totals</b>				<b>194</b>		\$ 18,334		\$ 2,974,999
<b>Intensive Outpatient - Special Populations</b>								
Mt. St. Joseph's	Adult	Intensive O/P	Women	9	\$ 25,006		\$ 225,055	
Mission Council	Intensive Outpatient	Intensive O/P	Sp. Speaking	15	\$ 9,367		\$ 140,509	
Potrero	ZAP	Intensive O/P	Youth, Young	12	\$ 19,975		\$ 233,629	
Sage	Mental Health O/P Match	Intensive O/P	Adults	5	\$ 7,500		\$ 37,500	
Sage	STAR	Intensive O/P	Women	12	\$ 21,620		\$ 259,439	
<b>Totals</b>				<b>53</b>		\$ 18,005		\$ 896,132
<b>Grand Totals</b>				<b>307</b>		\$ 19,266		\$ 5,088,296

\* Average Cost Per Static Slot - Weighted Average by Slot Number



# Housing First, Consumer Choice, and Harm Reduction for Homeless Individuals With a Dual Diagnosis

Sam Tsemberis, PhD, Leyla Gulcur, PhD, and Maria Nakae, BA

Current rates of homelessness in New York City are the highest ever documented.<sup>1</sup> A small percentage of this population remains chronically homeless, either living on the streets or other public places or intermittently using emergency rooms, shelters, jails, and other short-term services, but never successfully ending their homelessness.<sup>2</sup> Members of this chronically homeless group typically have a history of mental illness,<sup>3</sup> compounded by substance use disorders.<sup>4,5,6</sup> Although much is known about the chronically homeless, these individuals continue to elude existing program efforts.

The predominant service delivery model designed to address the needs of this chronically homeless population, called the Continuum of Care, consists of several program components. It begins with outreach, includes treatment and transitional housing, and ends with permanent supportive housing. The purpose of outreach and transitional residential programs is to enhance clients' "housing readiness" by encouraging the sobriety and compliance with psychiatric treatment considered essential for successful transition to permanent housing. This approach assumes that individuals with severe psychiatric disabilities cannot maintain independent housing before their clinical status is stabilized. Furthermore, the model presumes that the skills a client needs for independent living can be learned in transitional congregate living. Research in psychiatric rehabilitation indicates, however, that the most effective place to teach a person the skills required for a particular environment is within that actual setting.<sup>7</sup>

Consumers' perception of the Continuum of Care offers another divergent perspective. Consumers experience the Continuum as a series of hurdles—specifically, ones that many of them are unable or unwilling to overcome. Consumers who are homeless regard housing as an immediate need, yet access to housing is not made available unless they first complete treatment. By leveraging housing on participation and treatment, continuum program require-

**Objectives.** We examined the longitudinal effects of a Housing First program for homeless, mentally ill individuals' on those individuals' consumer choice, housing stability, substance use, treatment utilization, and psychiatric symptoms.

**Methods.** Two hundred twenty-five participants were randomly assigned to receive housing contingent on treatment and sobriety (control) or to receive immediate housing without treatment prerequisites (experimental). Interviews were conducted every 6 months for 24 months.

**Results.** The experimental group obtained housing earlier, remained stably housed, and reported higher perceived choice. Utilization of substance abuse treatment was significantly higher for the control group, but no differences were found in substance use or psychiatric symptoms.

**Conclusions.** Participants in the Housing First program were able to obtain and maintain independent housing without compromising psychiatric or substance abuse symptoms. (*Am J Public Health*. 2004;94:651–656)

ments are incompatible with consumers' priorities and restrict the access of consumers who are unable or unwilling to comply with program terms.

In addition, most consumers prefer to live in a place of their own rather than in congregate specialized housing with treatment services onsite.<sup>8,9</sup> Most programs have rules that restrict clients' choices and that when violated are used as grounds for discharging the consumer from the program. For example, despite having attained permanent housing, clients who relapse and begin to drink mild or moderate amounts of alcohol, may be evicted if the program has strict rules about sobriety maintenance. The chronically homeless population is characterized by its frequent inability to gain access to existing housing programs. Individuals in this group often have multiple disabling conditions, especially psychiatric conditions and substance abuse.<sup>10</sup> Most programs are poorly equipped to treat people with dual diagnoses, let alone prepared to address their housing needs.<sup>11</sup> Treatment requires time and commitment and is often not available if a program is under pressure to move clients along a continuum.<sup>12</sup>

The loss of control over one's life resulting from housing instability, frequent psychiatric hospitalizations, and intermittent substance abuse treatment leaves some consumers mis-

trustful of the mental health system and unwilling to comply with demands set by providers.<sup>13</sup> Others prefer the relative independence of life on the streets to a fragmented treatment system that inadequately treats multiple diagnoses or addresses housing needs.<sup>14,15</sup> Paradoxically, consumers' reluctance to use traditional mental health and substance abuse services as a condition of housing only confirms providers' perceptions that these individuals are "resistant" to treatment, not willing to be helped, and certainly not ready for housing.<sup>16</sup>

The Housing First model was developed by Pathways to Housing to meet the housing and treatment needs of this chronically homeless population. The program is based on the belief that housing is a basic right and on a theoretical foundation that includes psychiatric rehabilitation and values consumer choice.<sup>17</sup> Pathways is designed to address the needs of consumers from the consumer's perspective.<sup>18</sup> Pathways encourages consumers to define their own needs and goals and, if the consumer so wishes, immediately provides an apartment of the consumers' own without any prerequisites for psychiatric treatment or sobriety. In addition to an apartment, consumers are offered treatment, support, and other services by the program's Assertive Community Treatment (ACT) team. ACT is a well defined community based inter-

disciplinary team of professionals that includes social workers, nurses, psychiatrists, and vocational and substance abuse counselors who are available to assist consumers 7 days a week 24 hours a day. The Pathways program has made two modifications to the standard ACT model: a nurse practitioner was included to address the considerable number of health problems, and a housing specialist was added to coordinate the housing services. Although housing and treatment are closely linked, they are considered separate domains, and consumers in the program may accept housing and refuse clinical services altogether without consequences for their housing status. There are 2 program requirements: tenants must pay 30% of their income (usually Supplemental Security Income [SSI]) toward the rent by participating in a money management program, and tenants must meet with a staff member a minimum of twice a month. These requirements are applied flexibly to suit consumers' needs.<sup>21</sup>

Consistent with the principles of consumer choice, Pathways uses a harm-reduction approach in its clinical services to address alcohol abuse, drug abuse, and psychiatric symptoms or crises. At its core, harm reduction is a pragmatic approach that aims to reduce the adverse consequences of drug abuse and psychiatric symptoms.<sup>22</sup> It recognizes that consumers can be at different stages of recovery and that effective interventions should be individually tailored to each consumer's stage.<sup>23</sup> Consumers are allowed to make choices—to use alcohol or not, to take medication or not—and regardless of their choices they are not treated adversely, their housing status is not threatened, and help continues to be available to them.

Continuum of Care supportive housing programs subscribe to the abstinence-sobriety model based on the belief that without strict adherence to treatment and sobriety, housing stability is not possible. But studies examining the model's effectiveness report only modest results in achieving housing stability for individuals who are chronically homeless and mentally ill.<sup>24</sup> Alternatively, the approach used by the Pathways program assumes that if individuals with psychiatric symptoms can survive on the streets then they can manage their own apartments. The program posits that providing a person with housing first creates a foundation on which the process of recovery can begin. Hav-

ing a place of one's own may—in and of itself—serve as a motivator for consumers to refrain from drug and alcohol abuse.

The purpose of this study was to compare the effectiveness of the Housing First model with that of programs that used the Continuum of Care model for individuals who are chronically homeless and mentally ill.

We tested the following hypotheses: (1) the experimental (Housing First) group would report greater consumer choice over time than the control (Continuum of Care) group; (2) the experimental group would (a) exhibit lower rates of homelessness than the control group and (b) achieve and sustain greater residential stability than the control group; (3) the experimental group would exhibit rates of substance use similar to or lower than those of the control group; (4) the experimental group would participate in fewer substance-abuse treatments over time than the control group (i.e., because substance abuse treatment is not a precondition for the Housing First model, it is expected that there will be a lower rate of service utilization for the experimental group); and (5) the experimental group would exhibit rates of psychiatric symptoms similar to or lower than those of the control group.

## METHODS

### Participants

The 225 participants were randomized into 2 groups. One hundred twenty-six participants (56%) were assigned to the control group—and entered programs that followed the Continuum of Care model—and 99 (44%) were assigned to the experimental group and to a program that used the Housing First model. The control group was intentionally oversampled, anticipating that a higher number of control group participants may remain homeless and prove more difficult to locate for follow up interviews. The sample comprised 2 subgroups: an original street sample of 157 participants who met eligibility criteria, and a second group of 68 individuals recruited from 2 state psychiatric hospitals. To meet eligibility criteria, the first group had to have spent 15 of the past 30 days on the street or in other public places (shelters were not included), exhibited a history of homelessness over the past 6 months, and had an Axis I diagnosis<sup>25</sup> of severe mental illness.

Diagnoses were based on previous records from service providers or, in cases in which records were unavailable, on an interview with an independent psychiatrist. Although a diagnosis or history of alcohol or substance abuse disorders was not an eligibility criterion, according to clinical records 90% of all the participants also had a diagnosis or history of alcohol or substance abuse disorders. The street sample was recruited through service agency staff referral of eligible clients who were interested in study participation. The second group met the same entry criteria for homelessness and mental illness immediately before hospitalization as did the street sample.

Because of administrative problems, 12 participants in the experimental condition were not assigned a Pathways apartment, and 7 control participants were erroneously assigned a Pathways apartment. Excluding these 19 participants reduced the number of control participants to 119 (58%) and the number of experimental participants to 87 (42%).

As can be seen in Table 1, the final sample consisted of 162 (79%) men and 44 (21%) women whose average age was 41.3 years. More than half of the participants ( $n=110$ , 53%) were diagnosed with a psychotic disorder. Seventeen percent ( $n=35$ ) had become homeless before the age of 18 years. The longest period ever homeless, on average, was 4.5 years. Fifty-one percent ( $n=114$ ) of the participants were literally homeless (staying in the streets or public spaces) at the time of the baseline interview. Another 36% entered the study from psychiatric institutions but had been homeless before hospitalization. After randomization, there were no significant differences between groups for baseline demographic characteristics such as gender, age, education, race, diagnosis, or amount of time homeless.

### Procedures

After completing their baseline interviews, participants were interviewed every 6 months. Interviewers were blind to participants' assignment for baseline interviews but not for follow-up interviews. Data for the complete 24-month period were collected between December 1997 and January 2001. During each interim period, 5-minute telephone calls were conducted primarily to maintain contact with participants and establish their whereabouts. Par-



**TABLE 1—Participant Characteristics at Baseline (n = 206)**

	No. (%)
Study group	
Experimental	87 (42)
Control	119 (58)
Gender	
Female	44 (21)
Male	162 (79)
Age, y	
18-30	39 (19)
31-40	59 (29)
41-50	62 (30)
51-60	36 (17)
≥ 61	10 (5)
Education	
8th grade or less	21 (10)
Some high school	66 (32)
Finished high school	34 (17)
Completed general equivalency diploma	16 (8)
Vocational/trade/business school	5 (2)
Some college	49 (24)
College degree	10 (5)
Graduate degree	4 (2)
Race/ethnicity	
White (not Hispanic)	55 (27)
Black (not Hispanic)	84 (41)
Hispanic	30 (15)
Mixed/other/unknown	37 (18)
Diagnosis	
Psychotic	110 (53)
Mood-depressive	29 (14)
Mood-bipolar	29 (14)
Other	10 (5)
Unknown	28 (14)
Residence at baseline	
Streets/subways/parks/abandoned building/drop-in centers	114 (51)
Shelter/safe haven	13 (6)
Psychiatric hospital	80 (36)
Other	18 (8)

Participants were paid for all interviews. Six-month interviews were conducted in a variety of locations, including the research office, the participant's apartment/residential location, or a public place such as a cafe or restaurant. When it was not possible for interviews to be conducted face-to-face (e.g., the participant had moved out of state), interviews were conducted by telephone. For participants in psychiatric hospitals

and correctional facilities, research interviewers made onsite visits. The questions asked during each interview period remained the same. The follow-up rates by time period were as follows: 88% at 6 months, 87% at 12 months, 84% at 18 months, and 78% at 24 months. These follow-up rates do not include individuals who were missing at certain time points but who were located subsequently and for whom residential data was collected at a later point. Thus, the follow-up rates reported here are based on conservative calculations.

### Measures

A modified version of Consumer Choice, a 16-item, 5-point scale developed by Srebnik, Livingston, Gordon, and King,<sup>26</sup> was used to determine (1) how important it was for the participant to have choice at baseline and (2) how much choice the participant actually had, at subsequent time points, in their location, neighbors and housemates, visitors, and so forth.

We measured residential status with a 6-month residential follow-back calendar developed by New Hampshire Dartmouth Research Center.<sup>27</sup> The interviewer assessed the participant's location for each day during the past 6 months on a day-by-day basis. From this information, we calculated the proportion of time spent homeless as well as the proportion of time spent in stable housing.

Following the interview, the interviewer coded the participant's residential location according to several distinct residential categories. For the purpose of analyses, homelessness was considered as living on the streets, in public places, or in shelter-type accommodations. Residential stability was defined as residing in one's own apartment; or having a room or studio apartment in a supportive housing program, a group home, a boarding home, or a long-term transitional housing program; or living long-term with parents, friends, or other family members. The number of days spent in any of the locations categorized as "homeless" or "stably housed" was summed and divided by the total number of days of residency reported at the interview.

We measured alcohol and drug use with the Drug and Alcohol Follow-Back Calendar.<sup>28,29</sup> Participants reported the number of drinks consumed each day, as well as the number of days that selected drugs were used during a

6-month period. We used an alcohol use variable (measuring the total number of drinks) and a drug use variable (measuring the total number of days of drug use) for each 6-month period in the analyses.

We measured substance abuse treatment service utilization with a modified shorter version of the Treatment Services Inventory.<sup>30</sup> In the interview, participants were asked whether they received any substance abuse treatment during the past 2 weeks. Drug and alcohol treatment services use was indicated by an average of 7 items including questions asking whether the participant had received treatment in a detoxification program or other program; consulted with a counselor to talk about substance problems; or attended Alcoholics Anonymous, Narcotics Anonymous, or any other self-help group.

Psychiatric symptoms were measured with the Colorado Symptom Index,<sup>31</sup> a 15-item questionnaire including items assessing psychotic symptoms as well as symptoms related to mood and suicidality.

### Data Analysis

Repeated-measures analysis of variance (ANOVA) was used to examine group differences, during the 2-year follow-up period, for hypothesis 1 (consumer choice), hypothesis 2 (housing stability assessed as 2 separate outcomes: proportion of time stably housed and proportion of time homeless), and hypothesis 3 (substance abuse assessed as 2 separate outcomes: alcohol abuse and drug abuse). In cases in which repeated-measures ANOVAs yielded significant results, *t* tests were conducted to compare group differences at each time point. Group differences were then plotted and graphed for the 2 groups across time.

To appropriately examine differences in substance abuse treatment services use, hypothesis 4 was tested with a subsample of participants who were not on the streets but who were in some type of service-related program: namely, experimental participants who were currently housed by the Housing First program and control participants who were housed by one of the Continuum of Care programs. Control participants were included in this analysis if they reported that they lived most recently in one of the following places at the time of the interview: shelters, supportive housing programs,

drop-in centers, safe havens, detoxification facilities, crisis housing, intermediate care, boarding houses, transitional housing, group homes, alcohol/drug-free facilities, and treatment/recovery programs. Because participants' residential status changed from one time point to the next, the subsample also changed; we therefore had to conduct separate *t* tests for each time point. Because there were 5 time points, we used a Bonferroni adjusted  $\alpha$  of .025 to account for Type I error.

**Power Analysis**

To retain 80% power to detect an effect that explains 4% of the variance in the context of an equation (with 5 covariates) that explains 25% of the variance, we needed to retain 68% of the original sample; moreover, power for repeated-measures analyses would be higher.<sup>32</sup> Our retention rates were substantially above this figure, so we did not anticipate any problems in the power to detect group differences.

**RESULTS**

**Consumer Choice**

Results from repeated-measures ANOVA showed that there was a significant time  $\times$  group status effect, indicating that participants in the experimental condition perceived their choices to be more numerous than did participants in the control condition ( $F_{4,112}=8.91$ ,  $P<.001$ ). Additionally, the experimental

group's perceptions were more stable than were those of the control group. As can be seen from Figure 1, subsequent univariate analyses showed significant differences at 6, 12, 18, and 24 months, with the experimental group reporting significantly more choice than the control group.

**Residential Stability**

Repeated-measures ANOVA results showed a significant Time  $\times$  Group status effect. Participants in the experimental condition had significantly faster decreases in homeless status and increases in stably-housed status relative to participants in the control condition ( $F_{4,137}=10.1$ ,  $P<.001$ ;  $F_{4,137}=27.7$ ,  $P<.001$ ). As can be seen from Figures 2 and 3, subsequent univariate analyses showed significant differences at 6, 12, 18, and 24 months, with the experimental group reporting less time spent homeless and more time spent stably housed compared with the control group.

**Substance Use**

Repeated-measures analyses showed no significant differences in either alcohol or drug use between the 2 groups by time condition ( $F_{4,136}=1.1$ ,  $P=.35$  for alcohol use;  $F_{4,136}=.98$ ,  $P=.42$  for drug use).

**Substance Abuse Treatment Utilization**

Five *t* tests were conducted with an adjusted  $\alpha$  level of .025. As can be seen from Figure 4, these univariate analyses showed significant dif-

ferences at 6, 18, and 24 months ( $P<.025$ ) and at 12 months ( $P<.05$ ), with the Continuum group reporting significantly higher use of substance abuse treatment programs than the Housing First group. In addition, a decrease in service use occurred among the Housing First group and an increase occurred among the Continuum group over time.

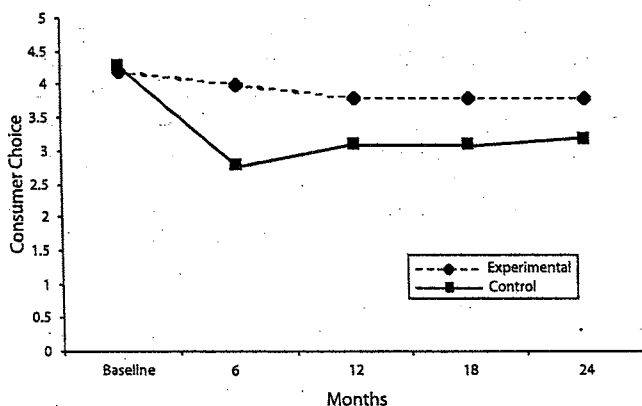
**Psychiatric Symptoms**

Repeated-measures analyses showed no significant differences psychiatric symptoms between the 2 groups by time condition ( $F_{4,137}=.348$ ,  $P=.85$ ).

**DISCUSSION**

Our results attest to the effectiveness of using the Housing First approach in engaging, housing, and keeping housed individuals who are chronically homeless and dually diagnosed. The Housing First program sustained an approximately 80% housing retention rate, a rate that presents a profound challenge to clinical assumptions held by many Continuum of Care supportive housing providers who regard the chronically homeless as "not housing ready." More important, the residential stability achieved by the experimental group challenges long-held (but previously untested) clinical assumptions regarding the correlation between mental illness and the ability to maintain an apartment of one's own. Given that all study participants had been diagnosed with a serious mental illness, the residential stability demonstrated by residents in the Housing First program—which has one of the highest independent housing rates for any formerly homeless population—indicates that a person's psychiatric diagnosis is not related to his or her ability to obtain or to maintain independent housing. Thus, there is no empirical support for the practice of requiring individuals to participate in psychiatric treatment or attain sobriety before being housed.

Participants' ratings of perceived choice—one of the fidelity dimensions of the Housing First program—show that tenants at Pathways experience significantly higher levels of control and autonomy in the program. This experience may contribute to their success in maintaining housing and to most consumers' choice to participate in treatment offered by the ACT team



Note. At baseline, participants were asked how much choice they would like to have. Subsequent time-points assess how much choice participants actually have.

FIGURE 1—Consumer choice in housing: baseline-24 months.

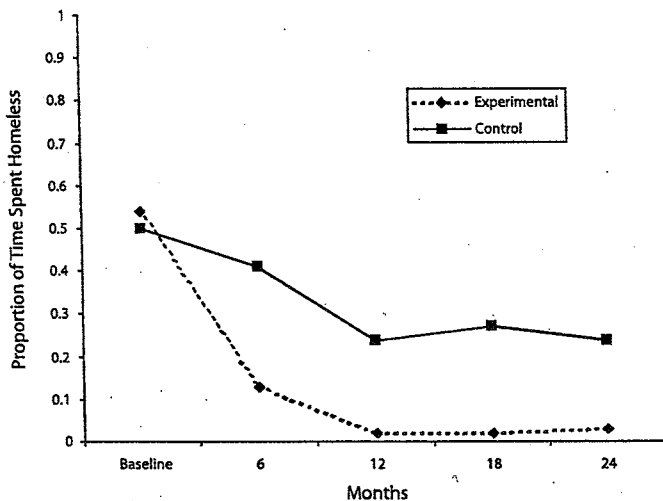


FIGURE 2—Proportion of time spent homeless: baseline–24 months.

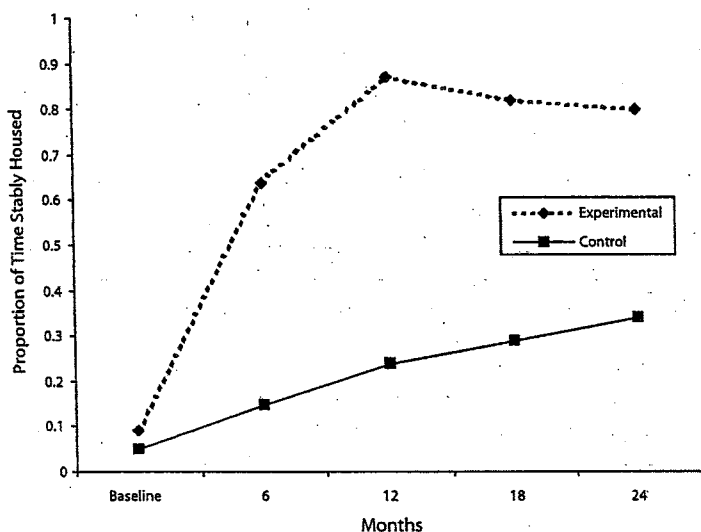


FIGURE 3—Proportion of time stably housed: baseline–24 months.

after they were housed. In addition, contrary to the fears of many providers and policymakers, housing consumers without requiring sobriety as a precondition did not increase the use of alcohol or drugs among the experimental group compared with the control group. Providing housing first may motivate consumers to address their addictions to keep their housing, so that providing housing before

treatment, may better initiate and sustain the recovery process.

Our findings indicate that ACT programs that combine a consumer-driven philosophy with integrated dual diagnosis treatment based on a harm-reduction approach positively affect residential stability and do not increase substance use or psychiatric symptoms. In addition, because the ACT teams were providing ser-

vices directly, substance abuse treatment services use was significantly lower for Housing First residents than for Continuum of Care residents. Because treatment for substance abuse is required, along with sobriety, by the Continuum of Care model, it is not surprising that individuals in the control group show greater use of treatment services. However, despite the control group's higher use of services, their levels of alcohol or drug use were not different from those of the experimental group. This disconnect between drug treatment services use and levels of drug use suggests that the control group may be using treatment facilities as short-term housing.

One limitation of the study is that self-reports of the use of alcohol and drugs and treatment services can be susceptible to reporting bias. Several studies have shown that among people who are homeless and dually diagnosed, there is a high rate of discrepancy between self-reports and client observation for substance use and for utilization of substance abuse treatment services.<sup>33,34</sup> Memory error, nondisclosure, social desirability concerns, and intentional misrepresentation can lead to reporting errors. Powerful systemic reasons for underreporting also exist. For example, participants enrolled in Continuum of Care residential programs, for which sobriety is mandatory, may be inclined to underreport the amount of drugs and alcohol consumed out of fear that such information may reach a caseworker or staff member and lead to the loss of their housing. Errors in self-reporting could be reduced if other measures (e.g., case manager's reports, laboratory drug tests) could be incorporated into a multiple-measure data report.

In conclusion, the outcomes achieved provide grounds for the rejection of the erroneous assumptions underlying the ubiquitous Continuum of Care model, the elimination of treatment requirements as a precondition for housing, and the support of initiatives adopting a Housing First approach to end homelessness and increase integration into the community for individuals with psychiatric disabilities living on our streets. ■

**About the Authors**

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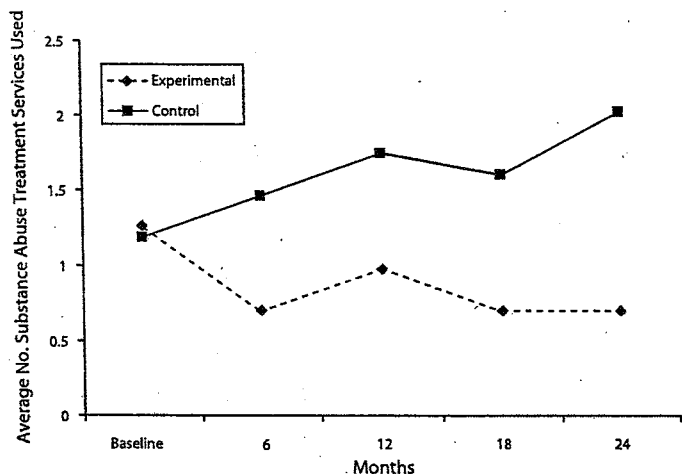


FIGURE 4—Average number of substance abuse treatment services used: baseline–24 months.

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#### Contributors

S. Tsemberis oversaw all aspects of the study and preparation of the article. L. Gulchur completed data collection and the statistical analysis. M. Nakae assisted with data analysis and literature review.

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#### Human Participant Protection

The protocol was approved by the institutional review boards of Pathways to Housing, Inc. and New York University. Informed consent was obtained from all participants.

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Residential Treatment Services Impacted by Proposed FY05-06 Initiatives

Agency	Program	Annual Cost Per		Average Cost per Bed	Beds	General Program Contract Amount	Subtotal By Group
		Slot*	Residential - Adults				
<b>Residential - Adults</b>							
CATS	Redwood Center	\$ 14,299	\$ 243,088		17	\$ 243,088	
Jelani	Start to Finish - Mens. Res	\$ 21,450	\$ 42,899		2	\$ 42,899	
Haight Ashbury	Western Addition	\$ 24,058	\$ 312,752		13	\$ 312,752	
Baker Places	Acceptance Place	\$ 39,275	\$ 471,302		12	\$ 471,302	
Walden House	Residential	\$ 24,448	\$ 2,151,626		94	\$ 2,151,626	
Friendship	Residential Treatment	\$ 26,073	\$ 94,872		12	\$ 94,872	
AARS	Therapeutic Community	\$ 31,921	\$ 492,514		18	\$ 492,514	
Walden House	SFGH Treatment Access	\$ 40,400	\$ 404,000		10	\$ 404,000	
Baker	Healy Place	\$ 47,520	\$ 570,244		12	\$ 570,244	
<b>Totals</b>			\$ 27,525		<b>190</b>	\$ 4,783,297	
<b>Residential - Special Populations</b>							
CATS	Golden Gate for Seniors	\$ 9,095	\$ 172,804		19	\$ 172,804	
Jelani	Recovery House	\$ 27,755	\$ 575,612		12	\$ 575,612	
Ohlhoff Recovery	Women's Residential	\$ 29,754	\$ 119,018		14	\$ 119,018	
St. Joseph's - Epiphany	Broderick House	\$ 36,000	\$ 360,000		10	\$ 360,000	
Walden House	Transgender Residential	\$ 36,658	\$ 329,926		9	\$ 329,926	
Jelani	Jelani House	\$ 52,156	\$ 350,218		14	\$ 350,218	
Latino Commission	Casa Quetzal	\$ 54,857	\$ 329,144		6	\$ 329,144	
Latino Commission	Perinatal Residential	\$ 58,716	\$ 352,297		6	\$ 352,297	
<b>Totals</b>			\$ 33,378		<b>90</b>	\$ 2,589,019	
<b>Overnight - Partial Day Special Populations</b>							
CATS	A Woman's Place	\$ 24,435	\$ 185,244		9	\$ 185,244	
Jelani	Newhall Manor	\$ 25,320	\$ 455,758		18	\$ 455,758	
Latino Commission	Casa Ollin	\$ 25,582	\$ 228,657		8	\$ 228,657	
<b>Totals</b>			\$ 25,838		<b>35</b>	\$ 869,659	
<b>Residential - Multi-Disordered</b>							
Walden House	WHITS	\$ 74,219	\$ 296,877		4	\$ 296,877	
Haight Ashbury	Center for Recovery	\$ 54,301	\$ 705,918		13	\$ 705,918	
<b>Totals</b>			\$ 58,988		<b>17</b>	\$ 1,002,795	
<b>Totals</b>			\$ 30,545		<b>332</b>	\$ 9,244,770	

\* Average Cost Per Slot calculation incorporates non-General Funds such as mandated set-asides, and incorporates that funding into the calculation.

Detoxification Programs						
Agency	Program	Annual		Average Cost per Bed	Beds	General Program Contract Amount
		Cost Per Bed*	Bed*			
<b>Residential Detoxification</b>						
St. Vincent De Paul	Howard St. Detox	\$ 19,935			38	\$ 706,906
Haight Ashbury	Smith House	\$ 36,446			8	\$ 291,644
<b>Totals</b>				\$ 22,808	46	\$ 998,550
<b>Residential Medical Detoxification</b>						
Baker Places	Page Street	\$ 107,979			6	\$ 647,875
Baker Places	Fremont Street	\$ 101,763			12	\$ 1,221,157
<b>Totals</b>				\$ 103,835	18	\$ 1,869,032
Totals					64	\$ 2,867,582
<b>Grand Totals</b>				\$ 32,978	396	\$ 12,112,352

\* Average Cost Per Slot calculation incorporates non-General Funds such as mandated set-asides, and incorporates that funding into the calculation.

Mental Health Residential Treatment Program				
Agency	Residential Treatment Program	Total	Total MediCal	Total General Fund
<b>Agency</b>				
Baker Places	Baker St	583,495	184,434	399,061
Baker Places	Grove-Crisis	815,146	257,655	557,491
Baker Places	Robertson*	762,245	240,934	521,311
Baker Places	Jo Ruffin Place*	960,298	303,536	656,762
Baker Places	San Jose Pl*	762,245	333,752	428,493
Conard House	Jackson St	707,615	241,592	466,023
Progress Foundation	Progress House	510,042	136,022	374,020
Progress Foundation	Carroll.-Rypins*	1,023,091	425,035	598,056
Progress Foundation	La Amistad	607,241	134,021	473,220
<b>Totals</b>		<b>6,731,418</b>	<b>2,256,981</b>	<b>4,474,437</b>

