

# A Randomized Clinical Trial of a New Behavioral Treatment for Drug Abuse in People With Severe and Persistent Mental Illness

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**Context:** Drug abuse by people with severe mental disorder is a significant public health problem for which there is no empirically validated treatment.

**Objective:** To evaluate the efficacy of a new behavioral treatment for drug abuse in this population: Behavioral Treatment for Substance Abuse in Severe and Persistent Mental Illness (BTSAS).

**Design:** Participants were randomly assigned to 6 months of treatment in either BTSAS or a manualized control condition: Supportive Treatment for Addiction Recovery (STAR).

**Setting:** Treatment was conducted in community-based outpatient clinics and a Veterans Affairs medical center in Baltimore, Md.

**Participants:** Participants were 129 stabilized outpatients meeting DSM criteria for drug dependence (cocaine, heroin, or cannabis) and serious mental illness: 39.5% met DSM-IV criteria for schizophrenia or schizoaffective disorder; 55.8%, for major affective disorders; and the remainder met criteria for severe and persistent mental illness and other Axis I disorders.

**Interventions:** Both treatments were administered by trained health care professionals in small groups, twice a week for 6 months. The BTSAS program is a social learning intervention that includes motivational interviewing, a urinalysis contingency, and social skills training. The control condition, STAR, is a supportive group discussion treatment.

**Main Outcome Measure:** The primary outcome measure was urinalysis results from twice-weekly treatment sessions.

**Results:** The BTSAS program was significantly more effective than STAR in percentage of clean urine test results, survival in treatment, and attendance at sessions. The BTSAS program also had significant effects on important community-functioning variables, including hospitalization; money available for living expenses; and quality of life.

**Conclusions:** The BTSAS program is an efficacious treatment. Further work needs to be done to increase the proportion of eligible patients who are able to become engaged in treatment.

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**D**RUG AND ALCOHOL ABUSE by people with severe and persistent mental illness (SPMI) is one of the most significant problems facing the public mental health system. These patients pose major problems for themselves, their families, health care professionals, and the mental health system. Lifetime prevalence of substance abuse was assessed at 48% for schizophrenia and 56% for bipolar disorder in the Epidemiologic Catchment Area Study,<sup>1</sup> and estimates of current abuse for the SPMI population range as high as 65%.<sup>2,3</sup> Substance use disorders in patients with SPMI begin early in the course of illness<sup>4</sup> and have a profound impact on almost every area of patient functioning and clinical care. Patients with SPMI with substance use

disorders show more severe symptoms of mental illness, more frequent hospitalizations, more frequent relapses, and a poorer course of illness than patients with a single diagnosis, as well as higher rates of violence, suicide, and homelessness.<sup>5,6</sup> They also have higher rates of incarceration,<sup>7</sup> greater rates of service use and cost of health care,<sup>8,9</sup> poorer treatment adherence, and treatment outcome.<sup>10,11</sup> Substance use also impairs information processing, which is particularly problematic for people with SPMI.<sup>12</sup>

There is an extensive literature on the treatment of patients with dual-disordered SPMI,<sup>13,14</sup> and there is a broad consensus on a number of elements required for effective treatment, including: (1) integration of both psychiatric and substance abuse treatment<sup>15-19</sup>; (2) conceptualizing treatment as

an ongoing process in which motivation to reduce substance use waxes and wanes<sup>20-22</sup>; and (3) a harm-reduction model is more appropriate than an abstinence model, especially during the early stages of treatment when the patient has uncertain motivation to change.<sup>23,24</sup> Conversely, there is a dearth of empirical data on effective techniques for producing change. This literature has been surveyed in 3 recent reviews, each of which used somewhat different criteria for identifying and evaluating trials. Drake et al were generally positive about the effectiveness of available treatments but concluded that "As yet there is little evidence for any specific approach to treatment. . . ." <sup>14(p368)</sup> Dumaine<sup>25</sup> reported that the largest effect size in studies covered by his review was 0.35 for intensive case management without a specific psychoeducational component. The largest effect size for a specific psychosocial treatment procedure was only 0.25. In the least optimistic view in the literature, Ley et al concluded that "There is no clear evidence supporting an advantage of any type of substance misuse program for those with serious mental illness over the value of standard care. No one program is clearly superior to another."<sup>26(p1)</sup>

In response to this dearth of empirically sound interventions, we developed a new, multifaceted treatment for substance abuse in patients with dual disorders that addresses the specific problems and needs of this population: Behavioral Treatment for Substance Abuse in SPMI (BTSAS).<sup>13,20</sup> The 6-month, small-group treatment includes 6 integrated components: (1) motivational interviewing to increase motivation to reduce use; (2) a urinalysis contingency applied in each session to enhance motivation to change and increase the salience of goals; (3) structured goal setting to identify realistic, short-term goals for decreased substance use; (4) social skills and drug refusal skills to enable patients to refuse social pressure to use substances and to provide success experiences that can increase self-efficacy for change; (5) education about the reasons for substance use and the particular dangers of substance use for people with SPMI to shift the decisional balance toward decreased use; and (6) relapse-prevention training that focuses on behavioral skills for coping with urges and dealing with high-risk situations and lapses. This article reports the results of a randomized trial in which BTSAS was compared with Supportive Treatment for Addiction Recovery (STAR), a manualized group comparison treatment, in 126 outpatients meeting criteria for SPMI and current dependence on cocaine, heroin, or cannabis. The study was approved and monitored by the University of Maryland School of Medicine (Baltimore) institutional review board.

## METHODS

### PARTICIPANTS

A total of 293 individuals provided informed consent, of whom 175 met *DSM-IV* criteria for current dependence on cocaine, heroin, or marijuana; had SPMI<sup>27</sup>; and completed baseline assessments. These 175 subjects were randomized to either BTSAS or STAR using an adaptive urn randomization procedure<sup>28</sup> that adjusted for sex, psychiatric diagnosis, drug of choice, and number of substance use disorders. A separate randomization was

conducted for participants recruited from community clinics and a Veterans Affairs medical center. This sample was predominantly male (63.4%), African American (75.4%), and had never been married (42.3%). Mean (SD) age was 42.7 (7.10) years, with 11.2 (2.28) years of education. Diagnostically, 38.3% met *DSM-IV* criteria for schizophrenia or schizoaffective disorder; 54.9%, for major affective disorders; and the remainder met criteria for SPMI and other Axis I disorders. The mean (SD) number of past psychiatric hospitalizations for the sample was 5.28 (7.97), and the mean (SD) age at onset of psychiatric disorder was 26.7 (10.8) years. The predominant drug of abuse was cocaine (68.6%), followed by opiates (24.6%) and cannabis (6.86%). Participants reported a mean (SD) of 5.73 (8.76) years of heroin use, 10.2 (8.21) years of cocaine use, 10.2 (10.4) years of marijuana use, and 12.1 (10.7) years of polydrug use. Participants were outpatients recruited from community clinics (58.9%) and a Veterans Affairs medical center in Baltimore. There were no differences between the groups on any psychiatric, drug preference, or demographic variables.

## TREATMENTS

Both treatments followed detailed manuals (available on request) and were administered to small groups (4-6 participants) twice per week for 6 months by trained therapists. Participants were entered into ongoing groups on completion of baseline assessments to minimize the delay between recruitment and treatment initiation. This rolling admission procedure also minimized the group effect (nonindependence) on individual participant data.

### Behavioral Treatment for Substance Abuse in SPMI

The BTSAS program is a highly structured social learning program that was developed by us specifically for people with SPMI. In creating the BTSAS program, we identified techniques that have been successfully used to treat substance abuse in less impaired primary substance-abusing populations (eg, contingency contracts, motivational interviewing) and modified the procedures to be applicable to people with SPMI. We also included treatment techniques to address issues that are particularly germane to drug abuse by people with SPMI. Recognizing that abstinence is a desirable goal but not one that can be easily achieved by people with SPMI, BTSAS uses a harm-reduction model in which small gains are reinforced and intermittent drug use is not punished. Given that motivation to reduce drug use waxes and wanes in this population, BTSAS attempts to increase motivation by conducting individual motivational interviewing<sup>29</sup> sessions at baseline, 3 months, and 6 months. In addition, a urinalysis contingency is applied in each session to serve as a motivational prosthesis. Subjects receive between \$1.50 and \$3.50 per session, increasing in \$0.50 increments for successive sessions with clean urine test results. The amount is reset to \$1.50 in the session following a dirty sample or an absence. To minimize failure experiences, achievable short-term goals are established in each session, and coping skills training is provided to prevent lapses from spiraling into full-blown relapses. A major factor contributing to drug use among people with SPMI is social pressure and the desire to seem normal. Hence, a considerable amount of time is devoted to social skills training<sup>30</sup> to teach participants how to refuse drugs, engage in alternative social activities, and develop non-drug using social contacts.

Each session adheres to the same basic structure: (1) A urine sample is secured and the results are announced to the group. Participants with negative samples receive social reinforce-

ment from the therapists and group members and financial reinforcement. Positive samples are followed by a nonaccusatory discussion of situational factors that contributed to use and rehearsal of coping strategies to increase the likelihood of abstaining in the situation in the future. (2) Each participant is then assisted in setting realistic goals for decreased drug use until the next session and signs a goal contract. (3) The remainder of each session follows a structured curriculum for drug abuse education, skills training, and relapse prevention.

### Supportive Treatment for Addiction Recovery

The STAR program is based on usual treatment at the university-run community mental health center from which many of our subjects are recruited. The groups are designed to be supportive and encouraging and to provide a safe and nonjudgmental place for participants to talk about substance use and their ideas and feelings about it. Some didactic education is provided about the effects of drugs and factors involved in reducing drug use when it fits into the discussion, but there is no formal curriculum or session-by-session plan regarding these issues. The group sets its own pace and determines its own topic, and the therapists encourage, but do not require, patient interaction. A urine sample is taken before each session, but no systematic feedback is provided.

The BTSAS and STAR programs were each administered by trained therapists (primarily masters degree-level health care professionals) who were supervised on a weekly basis throughout the project. All sessions were videotaped and fidelity of treatment administration was evaluated by blinded raters who independently rated randomly selected videotapes to assess adherence (22 yes or no items) and competence (14 items rated on 5-point Likert scales). The mean (SD) adherence ratings (proportion of adherent items) were 0.9771 (0.05) (range, 0.82-1.00) for BTSAS and 0.9722 (0.08) (range, 0.75-1.00) for STAR. The mean (SD) competence rating for BTSAS therapists (on a 5-point Likert scale) was 4.52 (0.33) (range, 3.80-5.00) and for STAR, 4.51 (0.41) (range, 3.60-5.00). The treatments were thus administered effectively and as dictated by the respective manuals.

### OUTCOME MEASURES

A primary outcome measure was urinalysis results secured at each treatment session attended. Urine samples were collected from all subjects at every session beginning in session 3, providing an objective measure of drug use throughout the 6 months of the trial. The second primary outcome was time until dropping out of treatment (dropout defined as missing 8 consecutive sessions). Secondary outcomes included achievement of 4 and 8 weeks of continuous abstinence and number of treatment sessions attended. Participants also completed a number of self-report measures at baseline and posttreatment, including the Addiction Severity Index (ASI),<sup>31,32</sup> the Substance Use Event Survey for Schizophrenia,<sup>33</sup> and the Brief Quality of Life Scale.<sup>34</sup>

### STATISTICAL ANALYSIS

Consistent with the literature,<sup>35</sup> we differentiated between individuals who failed to engage in treatment (attended  $\leq 2$  treatment sessions) and those who engaged in treatment and either graduated or dropped out. All analyses described later include all available data for the subjects who became engaged in treatment. The 2 primary hypotheses tested were that across the 6-month treatment period participants in BTSAS vs STAR would (1) produce a higher proportion of negative (clean) urine test results and (2) survive in treatment longer. The power analy-

sis conducted prior to initiating the study indicated that a sample of 110 would yield a power greater than 0.80 to detect a medium effect size at a conservative  $\alpha$  level of  $P < .01$ . After multiple-test Bonferroni adjustment, statistical significance is achieved with  $P$  value  $< .025$ .

To compare the mean proportion of clean urine test results provided by the 2 treatment groups, we used a logistic mixed-effects model (SAS macro GLIMMIX; SAS Institute Inc, Cary, NC), which allows different numbers of repeated observations (negative urine test results=yes/no) across subjects. A random-intercepts model was used to account for within-subject correlation among urine samples. A standard practice in analyzing urine data in substance abuse trials is to impute missing samples as positive (dirty), based partly on the assumption that absences are associated with drug use. This approach is consistent with an intent-to-treat analysis, but it can be misleading if there is high and/or unequal attrition. We therefore imputed (positive) urine values for missed visits in 2 ways, resulting in 2 analyses: (1) intermittent unexcused absences were assumed positive test results up until dropout; (2) all unexcused absences were assumed positive test results for the duration of the trial. This second method is more heavily weighted by attendance. In each case, we used the model to test for a treatment effect and estimated the relative odds of having a clean urine test result with a 95% confidence interval. Treatment groups had open enrollment, group size was small, and group dynamics were minimized by the structured training curriculum. Consequently, the effects of group membership were minimized and we did not include group as a factor in the analysis. In secondary analyses, we used the urinalysis data further to compare the 2 groups on 3 summary abstinence outcomes: percentage achieving 4 weeks, 8 weeks, and multiple 4-week blocks of continuous abstinence. We used 1-*df*  $\chi^2$  tests for these analyses.

To compare the treatment groups on length of time in treatment until dropping out, we used a simple Cox proportional hazards regression model. With this model, we tested for a difference in survival curves and computed the relative risk of dropout (hazard ratio). In a secondary analysis, we compared the 2 groups on number of days attended with a *t* test.

The ASI data was collected at baseline and posttreatment. We analyzed 2 key variables: number of drug days and number of days with drug problems. These variables were significantly zero-inflated; hence, we used a 2-part mixed-effects model specifically designed for zero-inflated distributions (SAS macro MIXCORR; SAS Institute Inc)<sup>36</sup> and that allowed use of all available observations. This model uses a 2-tier approach, simultaneously fitting a logistic regression model for change in proportion of nonzero drug days (among all participants) and a linear regression for change in mean number of drug or problem days (only among participants with any nonzero days.) With this analysis, we tested both within-group change and between-group differential change for both proportion of nonzero days and mean number of drug or problem days.

We conducted parallel analyses as for the ASI data for all other outcomes assessed at baseline and posttreatment using generalized estimating equations<sup>37</sup> for dichotomous outcomes and mixed-effects models for continuous and Likert-type scaled variables. These models were used so that all available data could be analyzed and to account for within-subject correlation over time.

## RESULTS

### RETENTION OF PARTICIPANTS

As shown in **Figure 1**, 293 subjects provided informed consent for the trial, of whom 175 completed baseline as-

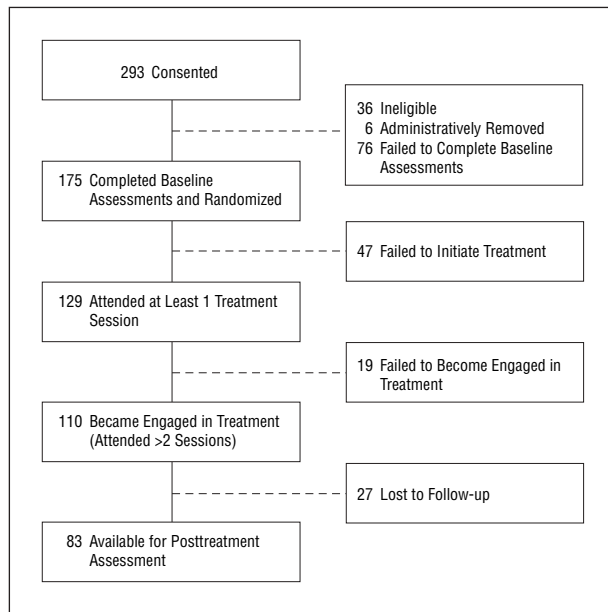


Figure 1. Subject flow.

assessments, met study inclusion criteria, and were randomly assigned to BTSAS or STAR. Attrition is widely recognized as a critical problem in substance abuse treatment programs, especially for participants with dual disorders.<sup>16,35</sup> Of the 175 participants who were randomized, 129 attended at least 1 session and 110 became engaged in treatment (BTSAS,  $n=61$ ; STAR,  $n=49$ ), 63% of those who completed baseline. Subsequent analyses are based on the engaged sample of 110. Subjects randomized to STAR were slightly more likely to become engaged in treatment than those in BTSAS (92.4% vs 80.3%;  $\chi^2=3.69$ ;  $P=.055$ ), but most of this difference reflects subjects who never began treatment and is therefore most likely a random effect. Comparison of the engaged BTSAS group and the engaged STAR group using  $\chi^2$  and  $t$  tests found no statistical differences between the 2 on demographic characteristics, diagnosis, or primary drug of abuse (Table 1).

As shown in Figure 2, BTSAS was significantly more effective than STAR in retaining subjects who became engaged in treatment (log-rank test for difference in survival curves,  $\chi^2=6.88$ ;  $P=.009$ ). The relative risk of dropout (hazard ratio) for BTSAS was about half that for STAR (hazard ratio, 0.51 [95% confidence interval (CI), 0.30-0.85]). Subjects in BTSAS also attended significantly more sessions: 29.0 vs 19.0 ( $t_{108}=3.50$ ;  $P<.001$ ; effect size, 0.64 [95% CI, 0.25-1.03].) That is noteworthy in this difficult-to-treat population because patients who attend drug treatment generally do better than those who do not.<sup>38,39</sup>

We further conducted a series of analyses to see if we could identify factors that discriminated subjects who became engaged in treatment from those who did not and dropouts, from subjects who completed treatment. There were no differences between those who became engaged in treatment and those who did not or between dropouts and those who completed treatment on any demographic or diagnostic factors or on primary drug of abuse. Subjects who became engaged in treatment reported fewer days of drug use on the ASI at baseline than

Table 1. Baseline Demographic and Clinical Characteristics of Participants Engaged in Treatment

	BTSAS (n = 61)	STAR (n = 49)	Total (n = 110)
Demographics, %			
Male	63.9	69.4	66.4
African American	77.1	71.4	74.6
Age, y, mean (SD)	43.8 (6.55)	41.6 (7.50)	42.8 (7.04)
Education, y, mean (SD)	11.7 (2.39)	11.8 (2.25)	11.7 (2.32)
Never married	50.8	38.8	45.5
Psychiatric, mean (SD)			
Schizophrenia/schizoaffective disorder, %	34.4	42.9	38.2
No. of previous hospitalizations	5.56 (10.3)	5.61 (7.55)	5.58 (9.16)
Age at onset of SMI	26.2 (11.2)	27.6 (9.57)	26.8 (10.5)
GAF at baseline	42.5 (8.22)	42.7 (8.58)	42.6 (8.35)
Substance use, %			
Current alcohol abuse/dependence	21.3	24.5	22.7
Goal drug			
Marijuana	1.64	10.2	5.45
Opiates	26.2	16.3	21.8
Cocaine	72.1	73.5	72.7

Abbreviations: BTSAS, Behavioral Treatment for Substance Abuse in Severe and Persistent Mental Illness; GAF, Global Assessment of Functioning; SMI, severe mental illness; STAR, Supportive Treatment for Addiction Recovery.

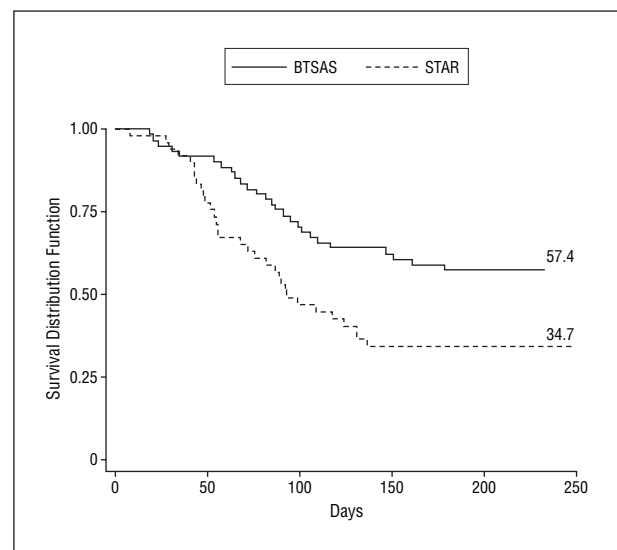


Figure 2. Survival in treatment. BTSAS indicates Behavioral Treatment for Substance Abuse in Severe and Persistent Mental Illness; STAR, Supportive Treatment for Addiction Recovery.

subjects who failed to become engaged in treatment (mean [SD], 5.61 [9.63] days vs 9.57 [12.5] days; Wilcoxon  $z=2.59$ ;  $P<.001$ ), but, as indicated later, the reliability of these self-report data are suspect. Moreover, subjects who completed treatment had a greater number of positive (dirty) drug screens at baseline than dropouts (mean, 79.3% vs 57.1% for dropouts;  $P=.06$ ), indicating that the trial was not limited to subjects with less severe drug problems. Overall, the data do not identify predictors of treatment participation or retention.

**Table 2. Urinalysis Data**

Outcomes	BTSAS (n = 61)	STAR (n = 49)	Group Comparison	P Value
Proportion of clean urine test results*	0.589	0.247	$F_{1,3671} = 16.05$	<.001
Proportion of clean urine test results†	0.466	0.142	$F_{1,5146} = 15.38$	<.001
Having at least one 8-week block of clean urine test results, %	32.8	8.16	$\chi^2_1 = 9.66$	.002
Having at least one 4-week block of clean urine test results, %	54.1	16.3	$\chi^2_1 = 16.6$	<.001
Having multiple 4-week blocks of clean urine test results, %	44.3	10.2	$\chi^2_1 = 15.3$	<.001

Abbreviations: BTSAS, Behavioral Treatment for Substance Abuse in Severe and Persistent Mental illness; STAR, Supportive Treatment for Addiction Recovery.

\*Missing urine samples imputed as positive through last session attended.

†Missing urine samples imputed as positive for all missed sessions.

## DRUG USE OUTCOMES

Urinalysis results are presented in **Table 2**. Subjects in BTSAS had a significantly higher proportion of clean urine test results during the 6 months of treatment than subjects in STAR, regardless of imputation strategy: mixed-model estimates, mean, BTSAS, 0.589 vs STAR, 0.247;  $F_{1,3671} = 16.05$ ;  $P < .001$ ; odds ratio, 4.4 (95% CI, 2.1-9.0) for imputation with missing urine test results assumed positive until time of dropout and mean, BTSAS, 0.466 vs STAR, 0.142;  $F_{1,5146} = 15.38$ ;  $P < .001$ ; odds ratio, 5.3 (95% CI, 2.3-12.1) for imputation with missing urine test results assumed positive for the duration of the trial. Treatment sessions were always separated by at least 2 to 3 days (eg, Monday-Wednesday, Tuesday-Friday), and the urinalysis tests used in this trial detect metabolites of cocaine and opiates during a 2- to 3-day period. Consequently, successive sessions attended with clean urine test results provide a rough estimate of periods of continuous abstinence. We examined 4-week and 8-week periods during which subjects attended every session, and these data show a pronounced advantage for BTSAS. Significantly more subjects in BTSAS had at least one 4-week block of continuous abstinence (54.1% vs 16.3%;  $\chi^2_1 = 16.6$ ;  $P < .001$ ), as well as multiple 4-week blocks (44.3% vs 10.2%;  $\chi^2_1 = 15.3$ ;  $P < .001$ ). More BTSAS subjects also had at least one 8-week block of continuous abstinence (32.8% vs 8.16%;  $\chi^2_1 = 9.66$ ;  $P = .002$ ). There were a small number of subjects whose primary drug of abuse was marijuana. Given that cannabinoid metabolites can be detected for up to 28 days, the overall rate of clean samples probably underestimates the amount of time not taking drugs.

We examined 2 ASI variables: number of drug days (in the prior month) and days with drug problems. Both variables were characterized by a large number of zero scores at both baseline and follow-up assessments and were analyzed as described in the "Statistical Analysis" subsection. There was no significant effect to suggest that one treatment had a more pronounced effect than the

other on either variable. However, these self-report data must be viewed cautiously because they were often in conflict with other sources of data on drug use. For example, of those participants who denied any drug use in the past 30 days on the ASI at baseline, 32.9% met DSM-IV dependence criteria on the Structured Clinical Interview for DSM-IV<sup>40</sup> and 9.33% had positive toxicology screens, suggesting that actual drug use during the prior month was considerably higher than was reported.

## OTHER OUTCOMES

We conducted post hoc, exploratory analyses on a number of ancillary clinical dimensions that are germane to outcomes and quality of life in patients with dual disorders. Given the low base rates of several of these variables (eg, inpatient admissions), we report within-group changes that might be informative, as well as between-group analyses. Participants in BTSAS had better outcomes than participants in STAR on a number of important clinical dimensions in addition to drug use. Inpatient admissions (psychiatric or substance abuse) declined from 29.5% in the 90 days prior to baseline to 6.5% in the 90 days prior to the posttreatment assessment for subjects in BTSAS ( $\chi^2_1 = 9.39$ ;  $P = .002$ ), compared with 20.4% and 16.2%, respectively, for STAR subjects ( $P = .30$ ). Prior to treatment, 46.6% of BTSAS subjects reported having enough money for food, clothing, housing, and transportation (Brief Quality of Life Scale) compared with 69.2% at the end of treatment ( $\chi^2_1 = 6.99$ ;  $P = .008$ ). This could reflect reduced expenditures on drugs. There was no change for subjects in STAR (43.8% prior to treatment and 51.5% afterward). Subjects in BTSAS also reported a small but significant increase in general life satisfaction (on the Brief Quality of Life Scale) from pretreatment to posttreatment (mean [SD], 4.25 [1.65] to 4.79 [1.66];  $t_{106} = 2.14$ ;  $P = .04$ ), and there was a significant increase in the overall quality of life (mean [SD], 3.97 [1.74] to 4.46 [1.68];  $t_{106} = 2.38$ ;  $P = .02$ ). Subjects in STAR failed to register a significant increase on either of these variables. There was also a significant reduction in the number of BTSAS subjects who reported being arrested (31% at baseline vs 12.8% at posttreatment;  $\chi^2_1 = 5.55$ ;  $P = .02$ ), compared with 22.9% and 27.3%, respectively, for STAR subjects ( $P = .51$ ). Finally, BTSAS subjects reported a significant increase in ability to independently perform activities of daily living on the Social Functioning Scale from baseline to posttreatment (mean [SD], 27.2 [7.43] to 31.5 [5.69];  $t_{107} = 3.73$ ;  $P < .001$ ). There was no comparable change for STAR subjects (baseline mean [SD], 27.3 [6.92]; posttreatment mean [SD], 28.1 [5.62];  $P = .51$ ). The interaction effect for this variable was significant ( $t_{107} = 1.98$ ;  $P = .05$ ).

The cost of administering the urinalysis contingency was relatively modest. Total payments to subjects were \$3676.50. The mean amount per subject was \$60.27, the median was \$51.50, and the range was \$0 to \$168.50. The average payment per session was \$2.29. Total cost of the urinalysis tests and associated supplies was (approximately) \$19 000.

## COMMENT

These data provide considerable support for the efficacy of BTSAS. Subjects in BTSAS achieved a mean of almost 59%

clean urine test results, compared with 25% for subjects in STAR. The biweekly urinalysis data provide an indication of cocaine and opiate use during the prior 2 to 3 days. Given that BTSAS subjects attended an average of almost 56% of sessions, that reflects a considerable amount of sobriety during the 6-month trial. While few participants achieved total abstinence, every day without drug use is associated with increased physical safety, increased likelihood of medication adherence, and decreased vulnerability to relapse in this population. In that regard, the data indicate that participants in BTSAS had decreased hospitalizations and arrests, more money available for daily expenses, and improved quality of life. The costs of the program, approximately \$372 per subject for the urinalysis contingency plus therapist time, are quite modest given that the benefits include a 23% reduction in inpatient admissions.

The comparator treatment, STAR, was not a diluted treatment as usual or a pseudotreatment designed to provide an easy target for an experimental intervention. The STAR program is a manualized version of a real treatment that is representative of quality care in a university-based clinic. Moreover, it was administered by trained health care professionals who videotaped sessions and received weekly supervision. Subjects were drawn from 3 different clinical settings and are representative of patients with serious psychiatric and substance abuse problems. Hence, these findings have meaningful public health significance.

The BTSAS program contains a number of different elements that each have potential clinical impact: motivational interviewing, goal setting, urinalysis contingency, social skills training, and relapse prevention. These elements were each included because they have had some reported positive effect with other populations and/or address particular problems associated with drug use by people with SPMI (eg, need to cope with social pressure). The current trial was designed as an efficacy study for the package, and it is not possible to empirically determine the relative contributions of each element. Our anecdotal observations suggest that each component contributed to overall outcomes, with differential importance for different participants. From a public health perspective, it would be desirable to evaluate the effects of the urinalysis contingency because the average cost ranged from \$7 to \$10 for the urinalysis and financial reinforcer. However, given the potential savings achieved from reductions in hospitalization, medical illness, unstable housing, and unemployment, this could be viewed as a modest expense.

The BTSAS program was effective in retaining participants who became engaged in treatment (attended  $\geq 3$  sessions). In contrast, 76 subjects (25.94%) who provided consent failed to complete baseline assessments, and 37.7% of those who completed baseline assessments failed to become engaged in treatment. This finding reflects a significant problem with any drug treatment. For example, of 1777 eligible persons screened by telephone for the National Institute on Drug Abuse Cocaine Collaborative Study, 937 (52.7%) attended an initial orientation session and 487 (52.7%) of those still eligible completed assessments and began the trial, 27% of the initial pool.<sup>41</sup> In a large naturalistic study of veterans with dual diagnoses referred for outpatient treatment, 53% failed to become engaged in treatment.<sup>42</sup> Similar results have been reported for a state hos-

pital sample<sup>43</sup> (42% attended their first outpatient visit), for patients discharged from a community hospital<sup>44</sup> (35% attended their first outpatient treatment session), and for patients entering a therapeutic community<sup>45</sup> (49% were lost to follow-up within the first 2 weeks).

Engaging patients with dual disorders in treatment is particularly difficult because most are ambivalent about the need to reduce their drug use and their desire for treatment waxes and wanes over time. Moreover, they frequently have difficult living situations, residual psychiatric symptoms, cognitive impairments, and financial constraints (eg, no money for car fare) that make it difficult for them to attend treatment. Several studies have examined the effects of structural procedures to increase engagement in treatment, such as providing mail and telephone prompts before sessions, providing an initial orientation session, scheduling sessions quickly after initial contact, and providing tangible benefits such as child care and car fare.<sup>46-48</sup> While many of these techniques should be used as part of good clinical practice, they have not proven to be sufficient to produce engagement in treatment. A more sophisticated approach, based on the Trans-theoretical Model of Change,<sup>20,49</sup> hypothesizes that patients unengaged in treatment need encouragement to move from the persuasion (precontemplation) or contemplation stage to the action stage of change. This has led to a number of trials that use versions of motivational enhancement therapy<sup>50</sup> to foster engagement by increasing motivation to change.<sup>23,51,52</sup> The published results for these approaches to date have been modest, at best. Moreover, our data and several published studies have failed to find a relationship between motivation to change and treatment participation,<sup>44,52,53</sup> raising questions about the hypothesis that increasing motivation to change is critical in this population.

We are currently conducting a trial using a 2-pronged intervention to increase engagement in treatment and thereby widen the applicability of BTSAS. The approach involves (1) a time-limited case management technique referred to as a critical time intervention to help develop a relationship between the treatment team and the patient and to help him or her overcome structural obstacles to treatment and (2) a time-limited psychoeducational intervention for concerned significant others (family members, friends) that aims to enlist them as partners to help connect the patient with treatment. Preliminary data suggest this approach may be highly effective. This trial will also provide further information in regard to the trend for early termination from BTSAS that was detected in the current study. Participants in BTSAS are faded into treatment to maximize engagement. They are not required to provide a urine sample for the first 2 sessions, and they are invited to observe the skills-training and goal-setting activities for 2 sessions before participating. Consequently, there is no obvious reason why patients would elect to terminate treatment in the first week. The new trial will help to determine whether this was a chance finding or if modifications to the protocol are warranted.

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