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12-STEP FACILITATION FOR THE DUALY DIAGNOSED: A RANDOMIZED CLINICAL TRIAL

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Abstract

There are few clinical trials of 12-step treatments for individuals with serious mental illness and alcohol or drug dependence. This randomized trial assessed the effects of adding a 12-session 12-step facilitation therapy (TSF), adapted from that used in Project MATCH, to treatment as usual in an outpatient dual diagnosis program. Participants were 121 individuals dually diagnosed with alcohol dependence and a serious mental disorder, followed during 12 weeks of treatment and 36 weeks post-treatment. Participants receiving TSF had greater participation in 12-step programs, but did not demonstrate greater improvement in alcohol and drug use. However, considered dimensionally, greater participation in TSF was associated with greater improvement in substance use, and greater 12-step participation predicted decreases in frequency and intensity of drinking. Findings suggest that future work with TSF in this population should focus on maximizing exposure to TSF, and maximizing the effect of TSF on 12-step participation.

Keywords

dual diagnosis; 12-step; alcohol dependence; serious mental illness; clinical trial; Alcoholics Anonymous; Double Trouble in Recovery

1. Introduction

A defining feature of 12-step treatment is the active facilitation of engagement in 12-step programs such as Alcoholics Anonymous (AA). There is now ample evidence that involvement in these programs has beneficial effects including improvement in drinking outcomes (e.g., (Emrick, Tonigan, Montgomery, & Little, 1993; Magura, Cleland, &

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Tonigan, 2013; Majer, Jason, Aase, Droege, & Ferrari, 2013; Moos & Moos, 2006; Tonigan, 2001; Tonigan, Connors, & Miller, 2003; Tonigan, Miller, & Connors, 2001; Tonigan, Toscova, & Miller, 1996; Zmore, Subbaraman, & Tonigan, 2013). Likewise, alcohol treatment based on the 12-step approach has a strong empirical basis, and may actually be superior to motivational enhancement and cognitive behavioral therapies with respect to abstinence-based outcomes such as complete abstinence and increased time to the first drinking day (Moos, Finney, Ouimette, & Suchinsky, 1999; Ouimette, Ahrens, Moos, & Finney, 1998; PMRG, 1997, 1998).

Because such findings are often based upon clinical samples that, due to eligibility criteria, systematically exclude those with co-morbid psychiatric disorders, less is known about the effectiveness of 12-step programs and treatment for seriously mentally ill patients. This is unfortunate, because, while estimates vary, it appears that between 41% and 65% of adults in the United States with substance use disorders have lifetime mental disorders (USDHHS, 1999), and between 25% and 45% of veterans presenting for substance treatment have co-occurring substance and mental disorders (Ouimette, Gima, Moos, & Finney, 1999). People with serious mental illness are at particularly high risk for substance use disorders. Lifetime prevalences of non-nicotine substance use disorders in people with schizophrenia and bipolar disorder were reported as 47% and 56%, respectively, in the Epidemiologic Catchment Area study (Regier, et al., 1990). The data that exist indicate that 12-step programs and treatments are effective for those with serious mental illness, but also suggest that psychiatric diagnoses, and psychosis in particular, may interfere with engagement and attenuate the beneficial effects (Bogenschutz, Geppert, & George, 2006; Jordan, Davidson, Herman, & BootsMiller, 2002; Timko, Cronkite, McKellar, Zmore, & Moos, 2013; Timko, Sutkowi, & Moos, 2010).

Dually diagnosed individuals (DDI) face a number of issues peculiar to the dually diagnosed that complicate their participation in 12-step programs. (Bogenschutz & Akin, 2000; Noordsy, Schwab, Fox, & Drake, 1996). For example, paranoia and social anxiety may make it very difficult for patients to participate in groups, especially when a confrontational style of interaction is employed, as it is in some 12-step meetings. Patients may feel they have little in common with the non-mentally ill members of the groups. They may be told that they are not clean and sober if they are taking psychiatric medication. In response to the difficulties experienced by some DDI in participating in traditional 12-step programs, specialized mutual help programs have emerged which aim to create a more welcoming mutual help community for the dually diagnosed. Specialized programs include Double Trouble in Recovery (DTR) (The Dual Disorders Recovery Book: A Twelve Step program for those of us with addiction and an emotional or psychiatric illness, 1993; Vogel, 1993), Dual Recovery Anonymous ("The Twelve Steps of Dual Recovery Anonymous," 1993), and Dual Diagnosis Anonymous (Monica, Nikkel, & Drake, 2010), among others. These programs have been designed by and for the dually diagnosed to create "a safe environment where clients can discuss the issues of mental disorders, medication, medication side effects, psychiatric hospitalizations and experiences with the mental health system openly, without shame or stigma" (*Double Trouble in Recovery: How to Start and Run a Double Trouble in Recovery Group*, 1998). Prospective studies involving 310 DTR participants followed for two years have demonstrated that DTR attendance significantly associated with abstinence, as well as improvements in self-efficacy, social support, and quality of life (Laudet, Cleland, Magura, Vogel, & Knight, 2004; Laudet, Magura, et al., 2004; Magura, Cleland, Vogel, Knight, & Laudet, 2007; Magura, Villano, Rosenblum, Vogel, & Betzler, 2008).

Although clinical use of the 12-step approach for mentally ill substance abusers is widespread, there are very few controlled studies of 12-step treatments specifically tailored to the seriously mentally ill (Brooks & Penn, 2003; Lydecker, et al., 2010; Magura,

Rosenblum, et al., 2008; Timko, Sutkowi, Cronkite, Makin-Byrd, & Moos, 2011), and none using an individual 12-step facilitation (TSF) approach. The principal aim of this study was to assess the efficacy of TSF, based on the Project MATCH TSF manual (Nowinski, Baker, & Carroll, 1992) but adapted for use with seriously mentally ill clients with alcohol use disorders, relative to treatment as usual. We hypothesized that participants receiving TSF in addition to treatment as usual would have greater increase in 12-step attendance and greater reduction in drinking than those receiving treatment as usual (TAU) alone.

2. Materials and Methods

Participants

All study-related procedures and materials were reviewed and approved by the Human Research Review Committee of the University of New Mexico Health Sciences Center. Participants were males and females of age 18 or older, currently receiving psychiatric treatment for any length of time in the outpatient Dual Diagnosis Program at The University of New Mexico Hospitals Psychiatric Center, Albuquerque, NM, recruited between April 2006 and June 2010. To be included in the study, participants were required to have 1) a psychotic disorder or a major affective disorder and 2) alcohol abuse or dependence, both active within the past 1 month. Diagnoses were ascertained using the Structured Clinical Interview for DSM-IV (SCID) (First, Spitzer, Gibbon, & Williams, 1996). In addition, participants were required to have two or more days of heavy drinking (5 or more drinks for per occasion for a man, 4 or more drinks per occasion for a woman) in the 30 days prior to screening, and to be willing to participate in specialized 12-step programs, able to provide informed consent, able to read, speak, and understand English at least the 5th grade level, and able to provide at least one contact person to assist in tracking for follow-up assessment. Potential participants were excluded if they were currently attending any 12-step program (two or more 12-step meetings in the past month), had unstable psychiatric illness or cognitive impairment of sufficient severity to render them incapable of informed consent or unable to participate in the TSF therapy or 12-step meetings, were actively suicidal or homicidal, had medical illness severe enough to compromise participation in the study, expected to be out of town or in jail for more than 21 days during the treatment period, or expected to participate in any other addiction treatment during the treatment period (not including TAU, 12-step programs, or other mutual support groups).

Two hundred and seventy-nine potential participants were contacted and briefly screened to assess if they met inclusion or exclusion criteria. One hundred and eighty (64.52%) initially met inclusion criteria. Informed consent was given by 142 participants (50.90%) who were thoroughly screened; 121 (43.37%) were randomized. Figure 1 provides a summary of reasons for exclusion from the study at each stage.

Randomization

Participants were randomized to the modified TSF condition vs. treatment as usual in a ratio of 2:1 using an urn randomization procedure. Variables included in the urn were 1) lifetime 12-step participation, using as a cut point the median lifetime attendance of 32 meetings which we found for patients in this clinic (Bogenschutz & Akin, 2000), 2) presence or absence of a psychotic diagnosis (schizophrenia, schizoaffective disorder, or psychosis not otherwise specified) based on SCID, 3) baseline percent days abstinent (PDA) from alcohol, 4) number of psychiatric hospitalizations in the past year, 5) motivation, based on the Taking Steps Scale of the SOCRATES (Miller & Tonigan, 1996), 6) gender, 7) presence or absence of an active drug dependence diagnosis, 8) social stability, from the Important People Interview (COMBINE_Study_Research_Group, 2003; Zywiak, Longabaugh, &

Wirtz, 2002), and 9) medication compliance, based on days of medication use in past 90 days from the Form 90.

Treatments

TSF—While the modified TSF approach retained the basic format of 12 weeks of individual TSF, significant content and process adjustments were made to adapt the manual for use with dually diagnosed clients. Modifications and rationale were as follows.

1. Because specialized 12-step programs for DDI appear to offer advantages beyond those of traditional programs, the therapy emphasized engagement in specialized dual-focus 12-step programs. However, AA or other 12-step involvement was encouraged if preferred by the participant, or if 12-step meeting attendance appeared to be limited by the availability of dual-focus meetings. The manual was specifically geared toward DTR because of the availability of DTR and lack of availability of other specialized 12-step programs in the city where the trial was conducted.
2. Throughout the 12-step facilitation therapy systematic attention was paid to the ways that psychiatric illness affects the addictive process, and vice-versa. This was to address the complex interplay between the co-occurring disorders which is an important part of the experience of being dually diagnosed, but is not addressed in standard TSF.
3. Two topics were added to deal with issues related to psychiatric illness. The first topic, adherence to psychiatric treatment as part of the recovery process, was added because medication non-adherence is a known cause of relapse for both psychiatric and substance use disorders in DDI (Coldham, Addington, & Addington, 2002). The second added topic was targeted social skills training to help patients tolerate meetings and interactions with individual 12-step program members such as the patient's sponsor. This topic was added to respond to the frequent patient complaints of being unable to tolerate groups, the well-known social skills deficits among seriously mentally ill patients (Brady, 1984), and some evidence that these skills deficits may interfere with attendance of and participation in meetings (Noordsy, et al., 1996).
4. The topics dealing with work on the fourth step (inventory) and family history were eliminated. It was thought that this work was too ambitious and potentially destabilizing to attempt with DDI in the context of a 12 week individual TSF. Patients were encouraged to engage in work on the fourth and following steps in the context of a stable relationship with a sponsor.
5. To facilitate attendance of meetings and therapy, the study provided assistance with transportation to and from DTR meetings and therapy appointments if participants were having difficulty arranging transportation on their own.
6. The therapist introduced the patient to at least one contact in DTR who is active in the program and clean and sober for at least a year. This DTR contact attended 30 minutes of the second session of the TSF therapy. Over 30 years ago Sisson and Mallams demonstrated the effectiveness of establishing contact between alcoholic patients and community AA members in increasing rates of AA attendance (Sisson & Mallams, 1981), and we believe that facilitation of this contact is likely to be at least as important for patients with serious mental illness.
7. Readings were selected from the Double Trouble in Recovery Basic Guide (DTR, 2000), a book published by DTR which covers the 12 steps from the perspective of the dually diagnosed. Participants were provided with a free copy of this book. We

believed the seriously mentally ill patients would be less likely to read extensively, and chose to “keep it simple” by focusing on a single resource which is accessible and relevant.

TAU—Treatment as usual (TAU) in the clinical dual diagnosis program was available to both experimental and control groups. Participants received their psychiatric treatment through an outpatient Dual Diagnosis team providing integrated treatment of severe mental illness and substance use disorders for dually diagnosed patients. The program included psychiatric treatment of chronic mental disorders and addictions, medication monitoring (e.g., disulfiram, naltrexone, depot antipsychotics) by the team nurses, individual therapy, and case management. Case management was provided on an as-needed basis, with approximately 25% of patients receiving case management at any given time. Addiction-related treatment was available through the dual diagnosis track of the psychosocial rehabilitation (PSR) program of UNMPC; but less than 10% of patients in the clinic were enrolled in psychosocial rehabilitation.

Therapist qualification and training—Therapists were licensed health professionals including two physicians, two nurses, a masters-level counselor, and a social worker. All had significant experience working with the dually diagnosed. Therapists received a 2½ day on-site training conducted by three of the authors (HV, MB, and JN) including didactic presentations, viewing of model videotapes and role play of sessions with simulated patients. To be certified, therapists were required to complete at least two training cases. In order to count toward certification, a case had to include at least 6 sessions and cover all core topics. Videotapes of these cases were reviewed and rated by the TSF supervisor (JN), and individual feedback was provided for each session in weekly phone supervision. A minimum level of competency (average of at least 80% on session guidelines) for each session was required for the candidate to be certified.

Therapist Supervision—In order to ensure fidelity to the TSF therapy, TSF therapists received telephone supervision weekly or biweekly during the study. For each therapist the supervisor reviewed all tapes for the first case following certification, and approximately three tapes per case for subsequent cases.

Fidelity monitoring procedures—Checklists of necessary elements for each session were developed to serve three purposes. 1) Therapists used them before and during sessions to maximize adherence to the protocol; 2) the therapy supervisor used the checklists in reviewing tapes of sessions to assess adherence; and 3) the checklists were used for formal fidelity monitoring. TSF treatment sessions were videotape recorded, reviewed, and coded by fidelity monitors using the session checklists. Overall performance ratings were based on percentage of checklist items rated positively, with a score of 80% or more required for acceptable performance. Fidelity Monitors were trained in the use of the adherence checklists by the TSF supervisor. Training included didactic sessions, review of the intervention manual, and group rating of practice tapes. To be certified, RAs were required to rate at least 10 training tapes and achieve adequate reliability relative to expert consensus ratings. A sub-sample of 58 tapes was coded by more than one rater to assess inter-rater reliability.

Assessment

Participants were assessed every 4 weeks during the 12 weeks of treatment and then every 12 weeks for 36 weeks after treatment, i.e., at weeks 24, 36, and 48 from the beginning of the study. Participants were compensated \$40 for each comprehensive assessment (baseline, 12, 24, 36, 48 weeks), and \$10 for the briefer week 4 and 8 assessments.

Substance use and consequences—The Form 90-A (Miller & Del Boca, 1994; Tonigan, Miller, & Brown, 1997; Westerberg, Tonigan, & Miller, 1998), developed for Project MATCH, was used as the primary measure of substance use. A Time-line-follow-back (TLFB) (L. C. Sobell & Sobell, 1995) was also administered at baseline and at months 1, 2, and 3 to confirm the reliability of self-report of substance use by dually diagnosed patients over a 90-day period. The TLFB has shown adequate to excellent reliability and validity over a wide range of research and clinical contexts, including psychiatric outpatients (Carey, 1997; L. C. Sobell, Brown, Leo, & Sobell, 1996; L. C. Sobell, Sobell, Leo, & Cancilla, 1988). Breath Alcohol Concentration (BAC) was measured at each visit. Temperature-monitored urines for urine drug screen were also obtained at each visit. The Short Inventory of Problems (SIP) past 3 month version (Miller, Tonigan, & Longabaugh, 1995), was used to measure consequences of drug and alcohol use.

Psychiatric symptomatology—We used the Brief Symptom Inventory (BSI) (Derogatis & Melisaratos, 1983) to measure the broad range of psychopathology expected among participants in this study. This self-report measure, derived from the longer SCL-90 (Derogatis, Lipman, & Covi, 1973), has been extensively validated and used in dually diagnosed populations (Baigent, Holme, & Hafner, 1995; Johnson, Brems, & Burke, 2002; Ross, Dermatis, Levounis, & Galanter, 2003; Velasquez, Carbonari, & DiClemente, 1999).

Treatment Participation—Participation in TSF was documented by the TSF therapist. Self-reports of treatment participation outside of the study were obtained from the Form-90. Objective measures of psychiatric treatment participation were obtained by review of psychiatric medical records at week 48. The number of appointments attended and appointments missed, days of attendance at PSR, psychiatric emergency visits, inpatient admissions, and inpatient days were recorded.

12-step-related behaviors—Twelve-step attendance was represented by two measures from the Form 90: a continuous measure of the proportion of days attending 12-step meetings in the assessment period, and a binary measure of any 12-step attendance in the assessment period. The 12-Step Participation questionnaire (TSPQ) was used to quantify participation in 12-step programs. The TSPQ is a 22-item instrument derived from the Alcoholics Anonymous Involvement Questionnaire (AAIQ), which was developed to assess both program and fellowship dimensions of AA behavior (Tonigan, Connors, & Miller, 1996). The TSPQ provided a measure of the 12 steps worked in the last assessment period, as well as a composite measure of five 12-step fellowship beliefs and practices (e.g. considering oneself a member of AA, reading 12-step literature, having a sponsor; Cronbach's $\alpha = 0.72$).

Data Analysis—Multi-level models (MLMs) were constructed in HLM version 6 (Raudenbush, Bryk, Cheong, Congdon, & du Toit, 2004) and included all participants, as HLM uses data from all participants to estimate model parameters. Separate analyses considered four dependent measures: (1) PDA, (2) drinks per drinking day (DPDD), (3) binary measure (yes/no) of complete abstinence from alcohol during the assessment period, and (4) proportion of days in the assessment period taking psychiatric medication. *A priori* primary outcomes were proportion alcohol abstinent days (PDA) and drinks per drinking day (DPDD). Tests of treatment group differences for drinking outcomes and medication adherence first examined treatment effects at end of treatment (week 12) and then at the final follow-up assessment (week 48). Preliminary analyses investigated whether participant psychiatric diagnosis interacted with group assignment or had a main effect in predicting drinking outcomes. None of these interactions or main effects were significant, thus diagnosis and a diagnosis by group assignment interaction was not included in the MLMs.

Models assessing outcomes at end of treatment or final follow-up were identical except for how time was coded: end-of-treatment analyses were centered at 12 weeks, and final follow-up analyses were centered at 48 weeks. Departures from normality led to using an arcsine transformation of PDA and percent days taking psychiatric medication. DPDD was a count variable and was modeled with the Poisson distribution for constant exposure, accounting for overdispersion. The binary alcohol abstinence outcome was assessed with the Bernoulli distribution. Intercepts were specified as random for all models and parameters were estimated using restricted maximum likelihood. Baseline values of PDA, DPDD, and percent days taking psychiatric medication were also modeled in level two to adjust statistically for individual differences, and were grand-mean centered. A baseline covariate was not specified in the MLMs assessing binary abstinence from alcohol as inclusion criteria required heavy drinking. Group assignment was coded as $-.5$ for TAU and $+.5$ for TSF and modeled as a fixed effect. A final outcome variable, the number of patient appointments with their psychiatrist during the study, was collected from patient charts and assessed once at the final follow-up period with a between-groups t -test.

To assess the effects of treatment on 12-step participation, eight additional MLMs were conducted assessing four different outcomes separately at 12 and 48 weeks: a binary measure of any 12-step attendance, the proportion of days in the assessment period attending 12-step meetings, step work, and 12-step fellowship beliefs and practices. These models were specified in the same manner as the MLMs reporting treatment effects for drinking outcomes and medication adherence.

3. Results

Description of sample

Eighty-three participants (68.6%) were randomized to TSF and 38 patients (31.4%) to TAU. There were 22 participants (18.2%) with a psychotic disorder, 43 (35.5%) with a bipolar diagnosis, and 56 (46.3%) with a diagnosis of major depression, and all 121 participants met criteria for a diagnosis of alcohol dependence or abuse, with 116 (95.9%) meeting criteria for current alcohol dependence. There was no treatment assignment by diagnosis interaction ($\chi^2(2, N=121) = 0.043, p = .98$). Baseline characteristics of treatment groups are listed in Table 1. Although an urn randomization procedure was used to form the treatment and control groups, significant differences in baseline characteristics between the two groups were observed. This was likely due to continuous variables being dichotomized for use in the urn procedure and due to the general principle that small sample sizes often produce greater variability (Maxwell & Delaney, 2004). The TSF group had significantly higher proportion days abstinent from alcohol at baseline. Members of the TAU group drank a significantly higher total standard quantity of ethanol, and were more likely to also have a concurrent diagnosis of drug dependence at baseline.

Treatment implementation

TSF—Patients attended an average of 5.5 TSF sessions (median 5). Fifty-six participants (67%) attended 3 or more sessions. Treatment fidelity was assessed by three independent research assistants and showed an average adherence rate of 89% based on checklist ratings. Although procedures were in place for managing fidelity falling below criterion, in practice all of the therapists were able to maintain satisfactory ratings. Inter-rater reliability of fidelity monitoring was calculated with Krippendorff's alpha using the KALPHA macro for SPSS (Hayes & Krippendorff, 2007). Fifty-eight of the 620 monitored TSF sessions (9%) were coded by more than one rater and inter-rater reliability was .74.

TAU—On average, study participants attended 6.05 (11.96) TAU visits although 49.1% ($n = 52$) of the participants did not attend *any* TAU (median = 1). The average number of TAU visits attended during the active 12-weeks of therapy did not differ between the two groups, TSF = 6.28 ($SD = 12.36$), TAU = 5.56 ($SD = 11.23$). Relatively equal proportions of participants in the TAU (44.7%) and TSF (42.2%) conditions reported no TAU attendance, ($\chi^2(2, N = 106) = .02, p = .89$).

Retention

Assessment rates were 97 (80.2%) at four weeks, 91 (75.2%) at 8 weeks, and 100 (82.6%) at the 12 week, end-of-treatment period. However, some missing data were reconstructed when participants were interviewed at later assessment intervals, increasing the assessment rates to 110 (90.9%) at 4 weeks, 106 (87.6%) at 8 weeks, and 107 (88.4%) at 12 weeks.

Follow-up rates were 93 (76.9%) at 24, 36, and 48 weeks. However, missing data were reconstructed from the self-report of participants when they returned for later assessment periods, increasing the follow-up rates to 100 (82.6%) at 24 weeks and 98 (81.0%) at 36 weeks. Four participants died during the follow-up period (three in the TAU group and one in the TSF group). Statistical analyses were conducted to investigate if attrition was predicted from treatment assignment or demographic characteristics. There was not a treatment condition-by-attrition interaction for the end-of-treatment assessment period $\chi^2(1, N=121) = 0.059, p = .81$, indicating that data were not differentially missing according to treatment group. Demographic characteristics such as gender, ethnicity, marital status, employment status, education, age, or household income did not predict attrition. However, there was a significant attrition by diagnosis interaction $\chi^2(2, N=121) = 6.72, p < .05$. Participants with a diagnosis of major depression had lower follow-up rates compared to those with a psychotic or bipolar diagnosis. Measures of baseline drinking frequency and intensity did not predict attrition at any time period.

Treatment Main Effects

Descriptive statistics for alcohol and substance use behavior, days in residential care, and proportion of days attending 12-step meetings are reported for each assessment interval by treatment group in Table 2.

12-Step Participation—Effects of treatment on four measures of 12-step utilization are shown at end of treatment in Table 3 and at the final follow-up assessment in Table 4. As shown, the TSF condition was effective relative to TAU in facilitating 12-step participation during the 12-weeks of treatment for three out of the four outcomes, and two measures showed a sustained increased at the final assessment. Specifically, over twice the percentage of participants in the TSF condition reported attending a 12-step meeting during treatment (65.8% versus 29.4%) and, on average, TSF participants attended significantly more 12-step meetings during treatment. Likewise, TSF participants reported, on average, significantly more overall engagement in 12-step fellowship activities and practices relative to the TAU participants. Effect sizes adjusted for small sample bias for the continuous measures of 12-step participation were moderate to large favoring the TSF group and ranged from $d = .48$ to $d = .73$. Between-group differences decayed for the continuous measure of 12-step attendance at the 48-week assessment, but TSF participants still reported more engagement in 12-step fellowship beliefs and practices, and more reported any 12-step attendance at week 48.

Substance use and psychiatric treatment adherence—MLMs assessing treatment main effects on substance use outcomes at end of treatment or final follow-up are shown in Tables 5 and 6, respectively. The linear time parameters in Table 6 are not shown because

they were identical to those reported in Table 5. Reported parameter estimates were from the unit-specific model with robust standard errors, and the intercept variance was significantly different from zero ($p < .05$) in each model. Treatment group differences were not observed on any of the four dependent measures at end of treatment (12 weeks) or at the final follow-up period (48 weeks), nor were they associated with change over time in any of the dependent measures. However, significant increases in PDA and the proportion of patients abstinent from alcohol were observed for the sample as a whole (time effect). Results also showed a significant decrease in

DPDD—The between-groups t -test assessing if there were significantly more psychiatric appointments attended by the treatment group during the course of the study was non-significant $t(114) = -0.293, p = .770$.

Dose-Response Post Hoc Analyses

Given the lack of a treatment effect on drinking outcomes in spite of the observed difference in 12-step attendance of the two groups, analyses were conducted to determine if there was a dose-response to TSF. These analyses paralleled the primary outcome analyses, the only difference being that instead of entering a binary term representing group membership into the HLM's we computed and entered a continuous variable that indicated the frequency of TSF sessions attended by TSF clients. All participants assigned to the TAU condition were assigned zeros, and participants in the TSF group were assigned the number of sessions they attended (0–12). Results differed substantially from the intent-to-treat analyses. Specifically, we found that number of TSF sessions was a significant predictor of both increased PDA *within* treatment, ($b = .013, t = 3.00, p < .01$) and at the 48-week follow-up ($b = .023, t = 2.04, p < .05$). Likewise, higher rates of TSF attendance predicted significantly lower drinking intensity (DPDD) within ($b = -.016, t = -2.54, p < .05$) and after treatment, ($b = -.05, t = -2.27, p < .01$). No significant relationships were observed between frequency of TSF attendance and alcohol-related consequences or the binary outcome representing complete alcohol and drug abstinence.

Effects of 12-step attendance on drinking

Lagged random coefficient regression analyses were conducted next to investigate how proportion days' 12-step attendance predicted later changes in drinking, regardless of treatment group assignment. Here, proportion of days attending 12-step meetings collected at baseline and at weeks 12, 24, and 36 were jointly used to separately predict PDA and DPDD collected at weeks 12, 24, 36, and 48. With only the random intercept, the lagged 12-step measure, and linear time terms entered into the model we found that 12-step attendance ($b = 0.13$) was a significant and positive predictor of later increases in PDA, $t(393) = 3.19, p < .002$. Likewise, in a similarly lagged model predicting DPDD we found that 12-step attendance significantly predicted later reductions in DPDD, $t(393) = -3.68, p < .001$. Post hoc analyses indicated that the effects of 12-step attendance on increased PDA and decreased DPDD were not moderated by treatment group assignment.

4. Discussion

The results of this study were mixed regarding the effects of the modified TSF intervention in the seriously mentally ill sample treated in this study. TSF had a significant effect on 12-step participation, which, however, was not accompanied by a significant decrease in substance use when compared with the TAU group. However, when TSF was treated as a continuous variable (number of sessions), it did predict improvement in PDA and DPDD both during and following treatment. Furthermore, 12-step attendance at each time point predicted abstinence at the following time point. On the basis of these results, we would

argue that rather than abandoning the 12-step approach for seriously mentally ill persons with alcohol use disorders, future studies should consider strategies to maximize exposure to TSF, and to maximize the effect of TSF on 12-step attendance.

The results of the dose-response analysis suggest that greater exposure to TSF might produce more robust effects. TSF participants in this study averaged only 5.5 (45%) of the maximum 12 sessions. Although this is not markedly less than treatment exposure in other TSF studies (e.g., 8.3 sessions in Project MATCH), the post-hoc dose-response analysis suggests that clinical benefit increases with the number of sessions. Contingency management or other incentives could be used to enhance treatment attendance. One should consider ways of lowering barriers to attendance such as transportation and scheduling. It is also possible that a maximum of 12 sessions in 12 weeks, although effective for treatment of non-dually diagnosed alcoholics, may not be sufficient for the dually diagnosed population. DDI tend to have a more chronic and relapsing course than for those with substance use disorders alone, and long-term approaches to treatment are thought to be more effective (Drake, Mercer-McFadden, Mueser, McHugo, & Bond, 1998). Likewise, it is possible that active engagement in 12-step programs, beyond mere attendance, may take longer to emerge.

TSF is hypothesized to work by increasing engagement in 12-step programs. The current study provides some further support for the belief that 12-step participation is associated with decreased substance use among dually diagnosed individuals. Increasing the potency of TSF with respect to its effect on 12-step attendance could increase its effect on substance use outcomes. Strategies could include more active linkage to 12-step meetings and members of 12-step programs. For example, one might have peer support workers meet more frequently with participants during the TSF treatment (we introduced participants to a peer DTR member in one of the TSF sessions). Peers could also provide transportation and accompany participants to meetings. Going one step further, the entire TSF could be provided by peer support specialists trained in the intervention and supervised by clinical staff. Case managers could also be used more actively to provide linkage. More extensive use of sheltered institutional meetings could decrease barriers to attendance.

Another possible reason for the relatively low 12-step meeting attendance in this study may have been the limited availability of specialized 12-step meetings. During the conduct of this trial there were only three to five DTR meetings available to participants, although a large number of AA meetings were available. Given the shortage of dual recovery meetings in many areas, further consideration could also be given to increasing emphasis on teaching dually diagnosed clients to negotiate successfully and benefit from traditional 12-step programs such as AA, as well as increasing the availability of specialized 12-step programs.

Finally, the recruitment strategy for this study may have selected for patients who were not highly motivated to change their drinking. All participants were actively enrolled in an outpatient dual diagnosis program which required participation in psychiatric treatment but did not require involvement in formal addiction treatment. Study therapists perceived considerable variability in the degree of interest that patients had in abstinence and in addiction treatment. Recruitment from other sources might have yielded a more highly motivated sample.

Several additional limitations should be mentioned. In spite of the use of urn randomization, the treatment groups differed significantly in alcohol use at baseline, with greater severity in the TAU group. Since more severe alcoholics often benefit more from 12-step, this might have biased the results in favor of TAU. The sample was quite heterogeneous with respect to

psychiatric diagnosis, and sample size was not sufficient to perform meaningful subgroup analyses.

Because of the limited 12-step participation in both treatment groups of this study, we cannot draw any firm conclusions concerning the value of 12-step participation in the dually diagnosed population. However, data from other sources provide strong evidence of benefit, although this benefit may be smaller than that experienced by non-dually diagnosed alcoholics. Therefore, we conclude that the 12-step facilitation approach for this population should not be abandoned, but that future work should focus on enhancing TSF exposure and identifying techniques that have a more robust effect on 12-step participation in this population.

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Figure 1.
Participant recruitment and attrition

Table 1Baseline Characteristics by Treatment Group ($N = 121$)^a

Demographics	TAU ($n = 38$)	TSF ($n = 83$)	<i>p</i>-value
Gender (% Male)	20 (54.1%)	14 (51.9%)	.83
Age in years	41.09 (8.60)	42.74 (9.42)	.38
Ethnicity			
Non-Hispanic White	17 (45.9%)	38 (48.7%)	.78
Hispanic	16 (43.2%)	29 (37.2%)	
Other	4 (10.8%)	11 (14.1%)	
Educational Attainment			
HS/GED Diploma	16 (64.0%)	27 (52.9%)	.65
Trade School/Assoc. Degree	7 (28.0%)	18 (35.3%)	
Undergraduate and Advanced	2 (8%)	6 (11.8%)	
Employment Status			
Unemployed	37 (81.1%)	60 (75.9%)	.76
Employed full/part time	5 (13.5%)	15 (9.0%)	
Retired/Homemaker	2 (5.4%)	4 (5.1%)	
Days paid for Work	11.03 (22.64)	7.93 (16.74)	.40
Days Incarcerated	2.16 (8.23)	2.31 (9.82)	.93
Total Institutional Days	4.45 (10.13)	4.92 (12.10)	.84
Substance Use/Consequences			
Drinks per Drinking Day	14.02 (8.75)	12.87 (8.82)	.51
Proportion Abstinent Days	.39 (.41)	.53 (.30)	.02
Alcohol-related Consequences (SIP) ^b	12.49 (3.01)	12.23 (3.29)	.69
Total Standard Ethanol Content	820.22 (707.42)	540.61 (470.89)	.01
Average Blood Alcohol Content	.25 (.21)	.24 (.20)	.83
Proportion Days Opium Use	.11 (.29)	.07 (.20)	.43
Proportion Days Marijuana Use	.19 (.31)	.12 (.24)	.15
Proportion Days Cocaine Use	.09 (.23)	.05 (.15)	.32
Current Drug Dependence Diagnosis ^c	18 (47.4%)	22 (26.5%)	.03
Help Seeking			
Proportion Days Formal Treatment	.06 (.15)	.05 (.09)	.77
Percent Attending any Treatment	22 (57.9%)	43 (51.8%)	.53
Proportion Days 12-step Attendance	.02 (.03)	.03 (.07)	.25
Percent Attending any 12-step meeting	15 (39.5%)	30 (36.1%)	.73
Adoption of 12-step Beliefs/Practices ^d	2.61 (2.11)	2.29 (2.00)	.43
Psychiatric Functioning			
SCID ^c diagnosis			
Psychotic	7 (8.4%)	15 (18.1%)	.98
Bipolar	13 (34.2%)	30 (36.1%)	
Major depression	18 (47.4%)	38 (45.8%)	
Brief Symptom Inventory			

Demographics	TAU (<i>n</i> = 38)	TSF (<i>n</i> = 83)	<i>p</i>-value
Global Severity Index	1.91 (0.82)	1.76 (0.74)	.31
Proportion Days taking Medication	.65 (.43)	.73 (.40)	.35
Psychological Change Readiness			
Readiness for Changing Alcohol Use ^e			
Ambivalence	14.24 (3.89)	14.45 (3.28)	.76
Problem Recognition	28.71 (6.23)	29.06 (5.19)	.75
Taking Steps	31.58 (7.34)	31.69 (5.90)	.93
Abstinence Self-Efficacy ^f			
Temptation	34.16 (18.60)	33.93 (17.62)	.95
Confidence	51.26 (13.99)	47.03 (15.53)	.16

^aFor continuous measures, table shows the mean, with standard deviation in parentheses. For categorical measures, the table shows the number of participants, with percentage in parentheses.

^bShort Inventory of Problems

^cStructured Clinical Interview for DSM-IV

^dSum of 7 items from the Twelve-Step Participation Questionnaire

^eStages of Change Readiness and Treatment Eagerness Scale

^fAlcohol Abstinence Self-Efficacy Scale

Table 2

Alcohol and substance use behavior, days in residential care, and 12-step attendance by treatment group

Measure	Baseline n = 121	12 weeks n = 107	24 weeks n = 100	36 weeks n = 98	48 weeks n = 93
Proportion days abstinent from alcohol					
TAU	.39 (.05)	.75 (.05)	.79 (.04)	.70 (.06)	.70 (.07)
TSF	.53 (.03)	.77 (.03)	.74 (.04)	.71 (.04)	.73 (.04)
Drinks per drinking day					
TAU	14.02 (1.42)	9.80 (1.38)	9.01 (1.29)	10.21 (1.26)	8.02 (1.19)
TSF	12.87 (0.97)	9.42 (0.94)	9.80 (0.98)	7.67 (0.90)	6.26 (0.82)
Proportion abstinent from alcohol					
TAU	0%	15%	10%	13%	17%
TSF	0%	11%	17%	18%	29%
Proportion abstinent from drugs					
TAU	83%	76%	73%	61%	72%
TSF	70%	60%	60%	63%	58%
Proportion abstinent from alcohol & drugs					
TAU	0%	6%	3%	6%	10%
TSF	0%	5%	7%	7%	13%
Days in residential care					
TAU	2.29 (1.09)	0.35 (0.18)	0.42 (0.20)	0.87 (0.45)	2.73 (2.60)
TSF	3.82 (1.44)	1.03 (0.47)	3.23 (1.67)	3.37 (1.36)	1.98 (1.22)
Proportion days 12-step attendance					
TAU	2%	3%	7%	5%	3%
TSF	3%	11%	11%	11%	9%

Table 3

12-step utilization at end of treatment

	<i>B</i>	Std Error	<i>t</i>	<i>p</i> -value
<u>Any 12-step attendance</u>				
For intercept				
Intercept	−0.371	0.133	−2.790	< .01
Baseline any 12-step attendance	1.818	0.293	6.211	< .001
Treatment group	0.882	0.271	3.255	< .01
For slope				
Time	−0.091	0.076	−1.203	.230
Treatment group	0.170	0.152	1.122	.263
<u>12-step attendance</u>				
For intercept				
Intercept	0.056	0.007	7.931	< .001
Baseline 12-step attendance	0.819	0.308	2.661	< .01
Treatment group	0.028	0.014	2.005	< .05
For slope				
Time	0.008	0.004	2.009	< .05
Treatment group	0.009	0.008	1.082	.280
<u>12-step work</u>				
For intercept				
Intercept	3.729	0.909	4.104	< .001
Baseline 12-step work	0.711	0.190	3.739	< .001
Treatment group	1.898	1.574	1.205	.231
For slope				
Time	1.099	0.605	1.818	.069
Treatment group	−0.177	1.213	−0.146	.884
<u>12-step fellowship beliefs and practices</u>				
For intercept				
Intercept	1.467	0.067	21.957	< .001
Baseline 12-step fellowship	0.420	0.060	7.000	< .001
Treatment group	0.438	0.138	3.168	< .01
For slope				
Time	−0.251	0.049	−5.151	< .001
Treatment group	0.094	0.098	0.968	0.334

Table 4

12-step utilization at final follow-up assessment

	<i>B</i>	Std Error	<i>t</i>	<i>p</i> -value
<u>Any 12-step attendance</u>				
Intercept	−0.644	0.282	−2.283	< .05
Baseline any 12-step attendance	1.818	0.293	6.211	< .001
Treatment group	1.393	0.571	2.441	< .05
<u>12-step attendance</u>				
Intercept	0.081	0.018	4.604	< .001
Baseline 12-step attendance	0.819	0.308	2.661	< .01
Treatment group	0.055	0.034	1.633	.105
<u>12-step work</u>				
Intercept	9.801	2.298	4.265	< .001
Baseline 12-step work	0.711	0.190	3.739	< .001
Treatment group	1.367	4.271	0.320	.749
<u>12-step fellowship beliefs and practices</u>				
Intercept	0.714	0.177	4.037	< .001
Baseline 12-step fellowship	0.420	0.060	7.000	< .001
Treatment group	0.721	0.358	2.013	< .05

Table 5

Treatment main effects at end of treatment

	<i>B</i>	Std Error	<i>t</i>	<i>p</i> -value
<u>Proportion days abstinent (PDA)</u>				
For intercept				
Intercept	0.791	0.021	37.496	< .001
Baseline proportion days abstinent	0.684	0.096	7.101	< .001
Treatment group	−0.011	0.045	−0.236	.814
For slope				
Time	0.081	0.014	5.804	< .001
Treatment group	0.014	0.028	−0.487	.626
<u>Drinks per drinking day (DPDD)</u>				
For intercept				
Intercept	2.293	0.037	62.553	< .001
Baseline drinks per drinking day	0.038	0.005	8.088	< .001
Treatment group	−0.040	0.071	−0.565	.573
For slope				
Time	−0.139	0.025	−5.617	< .001
Treatment group	−0.045	0.049	−0.916	.360
<u>Alcohol abstinence</u>				
For intercept				
Intercept	−3.224	0.269	−12.004	< .001
Treatment group	0.086	0.537	0.161	.873
For slope				
Time	0.598	0.085	7.002	< .001
Treatment group	0.289	0.171	1.694	.091
<u>Proportion of days taking psychiatric medication</u>				
For intercept				
Intercept	1.118	0.029	38.866	< .001
Baseline proportion days taking psychiatric medication	0.569	0.057	9.912	< .001
Treatment group	−0.054	0.059	−0.929	0.355
For slope				
Time	0.025	0.019	1.334	0.183
Treatment group	−0.059	0.037	−1.590	0.122

Table 6Treatment main effects at final follow-up ($N = 121$)

	<i>B</i>	Std Error	<i>t</i>	<i>p</i> -value
<u>Proportion days abstinent (PDA)</u>				
Intercept	1.034	0.054	19.104	< .001
Baseline proportion days abstinent	0.684	0.096	7.101	< .001
Treatment group	−0.051	0.110	−0.468	.640
<u>Drinks per drinking day (DPDD)</u>				
Intercept	1.876	0.093	20.186	< .001
Baseline drinks per drinking day	0.038	0.005	8.008	< .001
Treatment group	−0.176	0.188	−0.935	.352
<u>Alcohol abstinence</u>				
Intercept	−1.429	0.328	−4.353	< .001
Treatment group	0.955	0.657	1.454	.149
<u>Proportion of days taking psychiatric medication</u>				
Intercept	1.193	0.071	16.809	< .001
Baseline proportion days taking psychiatric medication	0.569	0.057	9.912	< .001
Treatment group	−0.232	0.143	−1.624	.107