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Comparison of Two Intensities of Tobacco Dependence Counseling in Schizophrenia and Schizoaffective Disorder

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Abstract

Compared to the general population, smokers with schizophrenia (SCZ) have reduced success in quitting smoking with usual approaches. This study tested two manualized behavioral counseling approaches – Treatment of Addiction to Nicotine in Schizophrenia (TANS) or Medication Management (MM) – for smokers who were motivated to quit. Individual counseling sessions were provided by mental health clinicians in mental health settings, along with nicotine patch. The two treatments varied in intensity and frequency of sessions. Eighty seven subjects were randomized and attended at least one treatment session. Twenty-one percent (n=18) of participants had continuous abstinence (CA) at 12 weeks after the target quit date (TQD), which was not significantly different between conditions (15.6% TANS vs. 26.2% MM, $X^2=1.50$; $p=0.221$). Smokers in both groups significantly reduced smoking as measured by cigarettes per day and expired carbon monoxide. Findings support that mental health clinicians can be trained to effectively help smokers with SCZ maintain tobacco abstinence.

1. Introduction

Individuals with schizophrenia or schizoaffective disorder smoke at rates nearly three times that of the general population, with prevalence rates of about 60% in a variety of studies (deLeon and Diaz, 2005; Hughes, Hatsukami, Mitchell, Dahlgren, 1986; Ziedonis et al., 2008). As with other smokers there is now ample evidence of negative consequences from tobacco in this group with regard to poor health and poor management of finances, in addition to the stigma and reduced quality of life suffered by smokers in general (Brown, Inskip, Barraclough, 2000; Dalack, Healy, Meador-Woodruff, 1998; Goff et al. 2005; Steinberg, Williams, Ziedonis, 2004). Smokers with schizophrenia are often highly nicotine dependent, have higher blood nicotine levels and lower than expected success rates in attempts to stop smoking, compared to smokers without this disorder (Covey, Hughes,

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Glassman, Blazer, George, 1994; Lasser et al., 2000; Williams et al., 2005; Williams et al., 2007; Ziedonis, Kosten, Glazer, Frances, 1994).

Given the continuing high rates of tobacco addiction in this population, there is a need to integrate nicotine dependence pharmacotherapy and psychosocial treatments into mental health treatment settings. Based on clinical experience and recent literature reviews and practice guidelines, pharmacotherapy for nicotine dependence (nicotine replacement or other FDA approved products) appears to be a necessity (Hitsman, Moss, Montoya, George, 2009; Kleber et al., 2006; Ziedonis et al., 2008). In addition, there appears to be a need to train mental health clinicians to provide behavioral therapy for this population, including how to integrate tobacco dependence treatment into their mental health treatment. This will include a role for educating clients about the use of pharmacotherapy to improve compliance.

Although psychosocial treatment is recommended as first-line evidence based strategy for smoking cessation, less than 5% of all smokers make use of behavioral interventions to help them quit smoking (Fiore et al., 2008). There have been several studies examining the effectiveness of smoking cessation treatments in schizophrenia although most have focused on pharmacological interventions such as nicotine patch or bupropion (Montoya & Vocci, 2007). These studies included counseling in the overall treatment approach; however the counseling was not the focus of the intervention. There have been fewer studies of intensive behavioral counseling for smokers with schizophrenia, and reported studies of combined interventions have study designs that make it hard to disentangle the effects of the psychosocial from the pharmacological intervention (Steinberg & Williams, 2007).

Addressing the unique problems of schizophrenia, including persistent symptoms, low motivation, poor social skills, cognitive limitations, and difficulty forming a therapeutic alliance may be critical in helping this population to quit smoking. Key aspects of an adapted behavioral treatment for tobacco dependence in smokers with schizophrenia should attempt to increase and maintain intrinsic motivation to change, improve self-efficacy to manage smoking cues which are prevalent in the environment and include the use of personalized feedback blended with relapse prevention and social skills training. Many of the skills necessary to quit smoking involve influencing one's social environment in some way and given deficits in social skills, enhancing this in treatment has been discussed in the literature (Addington, el-Guebaly, Campbell, Hodgins, Addington, 1998; George et al., 2000; George et al., 2002; Ziedonis & George, 1997). Avoiding triggers such as ubiquitous peers who smoke or finding activities during leisure time that do not involve smoking is important. Poor social skills associated with negative symptoms of schizophrenia (these include apathy, lack of emotion, poor or nonexistent social functioning) may make this difficult.

In general, there is a dose-response relationship with better smoking abstinence rates associated with more psychosocial treatment (total minutes of contact) during the quit attempt (Fiore et al., 2008). Community-based smoking cessation services for the general population are often brief in session length and time limited (about 4–6 sessions) (Fiore et al., 2008). Altered learning and information processing in schizophrenia require adaptations from traditional smoking cessation approaches. More and longer treatment sessions are needed to adequately cover materials, review key concepts and allow for in-session practicing of new skills. Several prior studies of smoking cessation in schizophrenia have included extra sessions prior to the quit date in order to provide more time for the use of motivational enhancement techniques (Addington et al., 1998; George et al., 2000; Ziedonis & George, 1997; Ziedonis & Trudeau, 1997). Additional time for client education is also essential with repetition of key concepts. Handouts also facilitate different learning styles and help reinforce medication information. In the delivery of motivational techniques, it is

helpful to provide personalized feedback via handouts and visual displays of information via graphs (Steinberg, Ziedonis, Krejci & Brandon, 2004).

There are currently only two published studies of smoking cessation in schizophrenia that emphasized the psychosocial treatment and included a quit date. George et al. (2000) found that while there were no statistically significant differences in abstinence rates at a 6-month follow-up evaluation between participants attending a standard American Lung Association group protocol and those attending a protocol focused on smokers with schizophrenia, those receiving the schizophrenia-focused protocol were significantly more likely to achieve continuous, four-week abstinence at end-of-treatment than those receiving the standard protocol. Baker et al. (2006) conducted a randomized controlled trial of a smoking cessation intervention among people with a psychotic disorder. The treatment condition included eight individual 1-hour sessions of motivational interviewing and cognitive behavior therapy plus nicotine patch, while the control group received treatment as usual, consisting of booklets for smoking cessation and nicotine patch. While this study found no overall differences between the treatment and comparison groups, there was a strong dose-response relationship between treatment session attendance and smoking abstinence and reduction. Attendance at 8 treatment sessions was associated with the highest continuous abstinence at 3 months, and no participants who attended fewer than five treatment sessions reported abstinence at any follow-up point (Baker et al., 2006). Building on our past clinical and research experience, we conducted a study examining two levels of intensity of individual counseling treatment for smokers with schizophrenia. In addition, this study trained mental health clinicians who had not done smoking cessation behavioral counseling previously in the context of a community-based mental health center.

2. Materials and Methods

This study tested two different intensities of behavioral counseling approaches – Treatment of Addiction to Nicotine in Schizophrenia (TANS) or Medication Management (MM) - for smokers with schizophrenia or schizoaffective disorder who were motivated to quit.

2.1 Subjects

Subjects were recruited from outpatient mental health facilities within the University of Medicine and Dentistry of New Jersey (UMDNJ)-University Behavioral Health Care (UBHC) system or Greater Trenton Behavioral Health Care systems. A total of 107 subjects who met DSM-IV criteria for schizophrenia or schizoaffective disorder gave their written informed consent to participate. The sample size was determined from estimates based on the literature of cessation outcomes from studies of smokers with schizophrenia and a medium sized effect in the expected abstinence rates between the 2 treatment groups. All subjects had their diagnosis of schizophrenia (SCZ) or schizoaffective disorder (SA) confirmed with the Structured Clinical Interview for DSM (SCID), smoked more than 10 cigarettes per day, and were willing to try to quit (Spitzer & Williams, 1985). Subjects also had to be taking an atypical antipsychotic to participate in order to eliminate the potential confounding factor of antipsychotic medication type (atypical vs. typical) and give patients the best chance at successful quitting (George et al., 2000). National data indicates that more than 75% of outpatients with schizophrenia are already on atypical antipsychotic medication (Leslie & Rosenheck, 2003). We did allow patients to enter the study who had been recently switched to an atypical antipsychotic medication as long as the dose was stabilized for one month prior to initiating treatment.

Seriously cognitively impaired patients were excluded and subjects were required to score 22 or higher on the Folstein Mini Mental Status Examination to be eligible (Folstein, Folstein & McHugh, 1975). Subjects with current use of clonidine, bupropion, nortriptyline

or any nicotine products (nicotine patch, gum, inhaler, lozenge or nasal spray) were excluded. Subjects who smoked cigars or used other tobacco products, including smokeless tobacco were also excluded. The study enrollment and treatment period went from September 2004 to March 2008. The Institutional Review Board of the UMDNJ -Robert Wood Johnson Medical School approved the protocol.

Although we consented 107 subjects, only 100 were randomized since two subjects did not complete screening and five were excluded for failing to meet SCID criteria for schizophrenia or schizoaffective disorder (2 subjects), health reasons that precluded use of nicotine patch (2 subjects), or not taking antipsychotic medication at baseline (1 subject). Randomization to one of the two unblinded study conditions (TANS vs. MM) was done using an adaptive urn randomization procedure that accounts for motivation, gender, ethnicity, and heavy (> 25 cpd) versus light smoking status (Stout, Wirtz, Carbonari, & DelBoca, 1994). Subsequent to randomization, an additional 13 were dropped from analyses because they did not attend even one session of behavioral treatment, leaving 87 subjects for analysis. Of note, we did compare the 87 study subjects who attended at least one session with the 13 subjects that did not attend even one treatment session and found that the two groups did not differ in any baseline demographic characteristics. All subjects were compensated for their participation in the study (\$30 for baseline, \$5 per treatment session, and \$30 for all other assessment points).

2.2 Measures

The baseline battery included assessments of smoking history, health history, demographics, psychiatric symptom measures, medications, other substance use (Addiction Severity Index (ASI)), and the Fagerström Test for Nicotine Dependence (FTND). Nicotine Dependence was diagnosed using DSM IV criteria. Readiness to stop smoking was assessed with the Importance-Confidence-Readiness Ruler (ICR) and a single item on motivation to quit smoking that asked subjects their current goal with regard to quitting that was described in a prior study (Heatherton, Kozlowski, Frecker, & Fagerström, 1991; McLellan, Luborsky, Woody, & O'Brien, 1980; Williams et al., 2005).

Baseline and follow-up assessments were completed by a research assistant who did not participate as a study therapist. Weekly assessments after the target quit date (TQD) included self report of smoking assessed by timeline follow back, expired CO level, and nicotine patch compliance (Sobell & Sobell, 1996). Expired carbon monoxide (CO) levels were assessed by having participants take a deep breath and hold it for 15 seconds before exhaling into a hand-held carbon monoxide monitor (EC-50 Smokerlyzer, Bedfont Scientific). Depressed mood (Beck Depression Inventory; BDI), and psychotic symptoms (Positive and Negative Syndrome Scale; PANSS) were assessed at 3, 6, and 12 months after quit date (Beck, Ward, Mendelson, 1961; Kay, Opler, Lindenmayer, 1989). Assessment of the therapeutic relationship between client and therapist was assessed with the Working Alliance Inventory (WAI) three months after quit date (Horvath & Greenberg, 1989). The primary outcome was continuous abstinence (CA) defined as self reported abstinence from tobacco after the TQD (not even a single puff) confirmed by exhaled carbon monoxide (CO) less than 10 parts per million (ppm).

2.3 Study Medications

All subjects received nicotine transdermal patch (Nicoderm CQ®) for a total of 16 weeks during the study, starting on the quit date (21mg for 12 weeks and 14mg for 4 weeks). Although willingness to take the nicotine patch was a requirement to enter the study, patients who were later not willing or able to use the patch were allowed to continue in the study and participate in counseling sessions. Subjects received education and handouts about

the use and benefits of nicotine patch. Compliance was monitored by visual inspection of the patch at counseling sessions and self-report of use between visits.

2.4 Behavioral Counseling

TANS was a high intensity treatment of 24 sessions (45 minutes) delivered over 26 weeks. MM was a moderate intensity treatment of 9 sessions (20 minutes) over 26 weeks. The smoking “quit date” occurred at week 5 of both behavioral therapy programs, and both included 16 weeks of nicotine patch beginning on the target quit date (TQD). Both treatments were designed to be “real world” interventions that could be replicated and fit into commonly scheduled outpatient sessions (20 vs. 45 minutes). Both approaches used an active, educational approach and therapists were encouraged to develop a collaborative and focused working alliance with clients. Treatment manuals, training programs, and training materials were developed to accompany the two approaches. Both approaches were organized into three stages of treatment (Engagement, Achieving Abstinence, and Relapse Prevention). Sessions also included a review of mental status and general medication compliance, but with a focus on the clinical issue of tobacco dependence. In both conditions, patients continued to receive their usual mental health treatment, including antipsychotic medications from their primary provider.

Medication Management (MM) consisted of nine sessions focused on quitting smoking that occurred over 26 weeks. Medication compliance and education about nicotine replacement therapy (NRT) are emphasized throughout and there are sections on monitoring psychiatric symptoms, and understanding medication interactions with tobacco. Although more intensive than brief interventions done in primary care settings, MM was designed with a real-world applicability for busy outpatient mental health clinicians with 20 minute sessions.

The TANS approach incorporates aspects of four well-established styles of treatment: Motivational Interviewing Skills, Social Skills Training, Use of Nicotine Replacement Medications and Relapse Prevention Techniques. These were chosen for their theoretical and empirical support as well as our prior experience using a similar blended therapy for treating other addictions in schizophrenia (Ziedonis & Stern, 2001; Ziedonis & Trudeau, 1997). TANS has more sessions prior to the quit date to enhance engagement into treatment and motivation to quit. Compared to MM, TANS has 15 additional sessions, and the length of each session is doubled, allowing the clinician to incorporate more intensive education and more time for feedback and role-play practice.

Both relapse prevention and social skills training share a common theoretical grounding in cognitive-behavioral theory and both were emphasized in the TANS approach. These techniques focus on the development of general coping strategies and specific skills that help prevent relapses and improve the patient’s functioning in everyday life. TANS emphasized practicing concrete coping skills in treatment sessions, with the goal of gradually generalizing these skills to real world situations. Utilizing role-plays in treatment sessions was a key aspect of TANS that allowed the client time to practice a particular skill (e.g. cigarette refusal) with their clinician instead of merely discussing it. Role plays and social skills training are traditionally done in group treatment, and this study adapted these techniques for role plays between the therapist and subject during the individual treatment. Role-plays were used to practice skills that would help the individual identify and cope with high-risk situations and moods which might otherwise precipitate relapse.

2.4 Clinician Training

Mental health clinicians were trained as therapists in the delivery of the TANS and MM treatments via a 2-Day didactic therapy training workshop and ongoing supervision. All

therapists were selected for consideration based on having more than 5 years of experience working with the seriously mentally ill and/or patients with chronic addictions. The goals of the smoking cessation behavioral therapy training program were for the therapists to understand and master the TANS and MM behavioral therapies, to maintain fidelity of the specific approaches, to avoid using techniques that were not part of either approach, and to ensure that different therapists used uniform procedures across different cases. Training faculty utilized visual, experiential, and verbal modalities, which were employed through lectures, role playing, and videotaped case illustrations. Since the same therapists delivered both TANS and MM, the training emphasized key differences in these approaches, and in maintaining fidelity for each approach.

The training was not designed to teach fundamental psychotherapy skills to novices, but to shape and focus the existing repertoire of skilled therapists in the area of treating tobacco dependence. Therapists were chosen who had prior clinical experience treating individuals with psychotic disorders although they may not have had prior tobacco dependence treatment training. After the training workshop, therapists participated in a “mock” therapy session of the TANS approach which was evaluated by the study leadership group for adherence and competence prior to seeing study cases. All treatment sessions were audio taped to ensure clinician adherence to protocol. Therapists also received a separate half-day clinical training session on Social Skills Training.

2.5 Ongoing Supervision of Casework

Each therapist was assigned cases from both study conditions in the randomized study. Therapists received ongoing weekly supervision throughout the study from doctoral level staff including the Co-PIs. Supervision provided for quality control monitoring and casework discussions on a weekly basis. This process aided in ensuring that the therapists continued to use the approach in accordance with the guidelines set forth in the manual and training. The supervisors also reviewed audiotapes of the treatment sessions that were discussed during supervision.

2.6 Statistical Analyses

Independent sample *t* tests (for continuous variables) and Chi-square tests of association (for categorical variables) evaluated the associations between smokers in both conditions for socio-demographic and clinical variables. Chi-square tests of association were used to determine the primary outcome of continuous abstinence from smoking at 12 weeks after TQD, quitting on the TQD and treatment session attendance. Backward stepwise logistic regression analyses were conducted to identify the predictors of quitting on the quit date. The variables entered into the model were age, education, gender, race, total FTND score, treatment group (TANS vs. MM), number of past quit attempts, expired CO at baseline, menthol cigarette smoking, awakening at night to smoke, other substance use in past 30 days, importance, confidence and readiness to quit at baseline, PANAS negative subscale, PANSS positive and negative subscale scores at baseline, BDI at baseline, and percent of treatment sessions attended. Regression analyses were repeated using the number of sessions attended prior to the TQD (rather than percent of total treatment sessions) to evaluate the importance of offering more sessions prior to the TQD. The criterion for eliminating variables from the model was set at *p* value greater than or equal to 0.10. Survival (life tables) analyses were done to examine the time to first cigarette lapse. Mixed model repeated measures ANOVA were done to examine smoking reduction outcomes and changes in symptom scores (PANSS, BDI) between groups. All analyses were done with SPSS version 16.0.

3. Results

3.1. Demographics of Study Population

No differences were found between subjects randomized to the TANS or MM treatment condition on most baseline smoking variables including mean cigarettes smoked per day, FTND scores, years smoked and age of first smoking (See Table 1). No differences were detected between groups on most illness characteristics including psychiatric diagnosis (schizophrenia vs. schizoaffective disorder), symptom severity of depression or psychosis, or antipsychotic dose, measured in chlorpromazine (CPZ) equivalents. Similar to other studies of the study population, subjects were mostly unemployed, never married, and with an educational level of high school or less. Motivation to quit smoking at baseline was not different between groups when measured by the single item smoking goal question or ICR ruler. There were differences in baseline CO (21.3 (MM) vs. 16.6 (TANS) ppm) though this measure is sensitive to recent smoking which was not controlled for in this study.

3.2. Abstinence Outcomes in Smokers with Schizophrenia or Schizoaffective Disorder

Twenty-one percent ($n=18$) of participants had continuous abstinence (CA) at 12 weeks after the Target Quit Date (TQD), which was not significantly different between conditions (15.6% TANS vs. 26.2% MM, $X^2=1.50$; $p=0.221$). The mean expired CO of all subjects who reported abstinence at week 12 was 2.5 ppm (SD 2.6), validating their self-report. The 7-day point-prevalence abstinence measured as self-reported no tobacco use in the past 7 days prior to week 12 after TQD (and confirmed by CO) was approximately the same as the CA rate ($N=20$; 23.0%) and not different between treatment groups.

The follow-up rate was 87.4% ($n=76$) at 6 months and 74.7% ($n=65$) at 12 months and not different between groups. Seventeen percent ($n=15$) of participants had continuous abstinence (CA) at 26 weeks after the Target Quit Date (TQD), which was not significantly different between conditions (7, TANS and 8, MM; $Chi-square=0.667$, $DF=1$, $p=0.779$). The mean expired CO of all subjects who reported abstinence at week 26 was 2.4 ppm (SD 2.6), validating their self-report. Fourteen percent ($n=12$) of participants had self-report continuous abstinence (CA) at 1 year after the Target Quit Date (TQD), which was verified by CO at time of visit. Abstinence at 1 year was not significantly different between conditions (6, TANS vs. 6, MM, $Chi-square=0.017$, $DF=1$, $p=0.898$).

We also did a survival analysis to measure the time to first cigarette lapse (defined as any use) which was measured in days from TQD to 12 week follow-up ($N=69$ subjects who smoked in the first 12 weeks). The time to first cigarette lapse was not different between treatment groups (Wilcoxon statistic 0.996, $df 1$, $p=0.318$). The mean time to first cigarette lapse was 5.1 (TANS) vs. 6.3 (MM) days (NSS).

3.3. Quitting on the Quit Date

Since the TANS condition included additional sessions prior to the TQD, we examined secondary outcomes including percentage of subjects who were able to quit smoking for at least one day (quit on the TQD). In the entire sample, forty-six percent of subjects ($N=40$) quit on the TQD, although this was not different between treatment groups (44.4% TANS vs. 47.6 % MM, $X^2(1)=0.88$, $p=0.767$).

Among smokers who attended at least one treatment session ($N=87$), smokers who quit on their quit date reported lower baseline confidence in their ability to quit smoking than those who did not quit smoking on their quit date ($t(85) = 2.10$, $p = .039$). Confidence to quit measured at baseline on the ICR subscale was similarly lower in those who quit on their TQD (6.4) compared to non-quitters (7.6).

Backwards stepwise regression analyses were done to determine the effects of patient characteristics, smoking history, level of nicotine dependence, motivation to quit and attendance at treatment sessions on quitting on the TQD. Results of these regression analyses indicate that number of sessions attended (pre-TQD), age, years smoking, and lower confidence (ICR subscale) significantly predicts quitting on the TQD.

3.4. Reduced Smoking Outcomes in Smokers with Schizophrenia or Schizoaffective Disorder

We did a 2×2 mixed model repeated measures ANOVA to examine changes in expired CO during the study (from baseline to week 17). There was an overall significant reduction in expired CO in subjects (from 19.0 ppm at baseline to 14.5 ppm at week 17; Wilks' Lambda 0.865, $p<0.001$), but there were no differences in CO reduction between the TANS and MM groups (Wilks' Lambda .999, $p=0.758$).

We also did a 2×2 mixed model repeated measures ANOVA to examine reduction in cigarettes smoked per day (cpd) during the study (from baseline to week 17). There was an overall significant reduction in cpd in subjects (from 24.6 at baseline to 13.1 at week 17; Wilks' Lambda 0.608, $p<0.001$), but there were no differences between TANS and MM groups (Wilks' Lambda 0.984, $p=0.351$).

3.5 Effect of Treatment on Clinical Symptoms of Schizophrenia

We evaluated changes in symptom score from baseline to week 17 of treatment between groups using 2×2 ANOVA. There was no differential change between groups on the BDI (Wilks Lambda 0.991, $p=0.406$), PANSS positive subscale (Wilks Lambda 1.000, $p=0.899$), and PANSS negative subscale (Wilks Lambda 0.993, $p=0.488$). We also compared changes in the BDI and PANSS positive and negative subscale scores to examine smokers versus those who had achieved abstinence using 2×2 ANOVA and found no differences. This was consistent with our clinical data from adverse event reports that indicated no evidence of worsening of psychosis or mood symptoms in subjects that was related to participation in the treatment trial.

3.6 Treatment Session Attendance

We further evaluated the impact of total session attendance on outcome. There is a positive association between the percentage of sessions attended and 3-month smoking cessation outcome. The higher percentage of total sessions subjects attended (regardless of treatment condition), the more likely subjects were to be abstinent from cigarettes at 3 months ($\chi^2(2)=12.707$, $p<0.01$).

Consistent with Baker et al. (2006), we report comparisons between groups defined on the basis of session attendance, divided into thirds. Results are shown in Table 3. Participants who completed 7 or more MM sessions or 9–16 TANS sessions had higher odds of 3 month continuous abstinence (NSS).

3.7 Therapeutic Alliance

In the total sample (N=87) subjects who had a high WAI global rating score at 3 months were more likely to be abstinent at three months ($p=.029$). There were however no differences in WAI global rating scores between TANS and MM participants ($p=.606$). There was also no correlation between percent of sessions attended and WAI global rating score.

4. Discussion

Tobacco dependence is a major public health problem and a key factor in explaining why people with schizophrenia have reduced life expectancy and more premature death due to cardiovascular disease (Brown, et al., 2000; Goff, et al., 2005). There is a great need to develop more effective smoking cessation interventions that can be delivered in the mental health treatment setting by mental health clinicians. Interventions, which are effective in primary care and public health settings, appear to lack the ability to attract individuals with schizophrenia to attend, and clinicians in these settings have not been trained on the special clinical needs and demands for treating individuals with schizophrenia.

To our knowledge, this is the first study to incorporate training mental health clinicians on smoking cessation behavioral therapy and to test the efficacy of their delivering the treatment in two different real-world individual treatment session durations (45 minute versus 20 minute sessions). Additionally, our embedded treatment model that allowed smokers to receive the study treatment in their usual treatment setting enhanced the feasibility and real-world aspects of the design.

Overall, the rates of continuous abstinence (CA) in this trial were better than those previously published at 12 weeks after TQD; however there were no differences in treatment outcome between the lower and higher intensity treatments. Self-report measures in this study were validated with weekly expired CO levels. Although both treatments resulted in similar abstinence rates, both are strikingly different from typical smoking cessation interventions offered in the community. Even the briefer of the two treatments in the study (9 individual sessions of 20 minutes per session) is more intensive than most smoking cessation treatments for the general population.

Both TANS and MM shared an awareness of the psychopathology associated with schizophrenia and both were delivered in the context of the mental health setting. For both TANS and MM, the therapy style was simple and encouraging with ample repetition and time for psychoeducation. During sessions, therapists would check in to assess progress or changes in both the tobacco use and the mental illness symptoms of each subject. Continued education on the correct use of the nicotine patch was emphasized and included frequent compliance checks. Varying levels of motivation among subjects in the study were expected and therapists were guided in using specific techniques for smokers trying to quit as well as for those who were ambivalent or not motivated. These treatment principles that made both TANS and MM well suited for smokers with schizophrenia may have reduced the additional effects of treatment session intensity and our difficulty to assess differences between them.

In designing this study we gave much consideration to the issue of designing an individual versus a group treatment approach. We decided to make the primary focus of treatment individual to give smokers the greatest possible benefit from the motivational techniques. We also felt that individual counseling could be more generalizable and easier to integrate into mental health settings given current reimbursement practices. A potential limitation of individual counseling is that it may hinder role-plays that benefit from the group setting. Therapists in this study reported some difficulties implementing role plays during counseling sessions despite training in these techniques and supervision that included listening to audiotaped sessions. The group setting may enhance role playing, allowing for analyzing problems from various perspectives and developing teamwork, cooperation and creative problem solving.

We found a positive association between the percentages of sessions attended and better smoking outcomes at the quit date and 3 month outcomes. Consistent with Baker et al. (2006), participants who had better attendance at individual sessions had better outcomes.

Since we cannot establish causality in our analyses we can hypothesize 2 possible explanations: that better attendance resulted in improved abstinence outcomes or that greater success in quitting predicts better subsequent attendance.

Although this study focused on comparing two psychosocial treatments, the study was designed so that all subjects would receive nicotine patch. Overall, compliance with nicotine patch was good and no patients suffered any adverse events from nicotine patch. We also developed a successful model of distributing and supervising patient use of an over-the-counter nicotine replacement product in mental health settings by non-prescribers. This approach was feasible with few difficulties and resulted in many patients receiving access to nicotine patch. A limitation of our study was that we used only nicotine patch which may not have delivered enough nicotine replacement to some smokers. This may be particularly important as studies have shown that smokers with schizophrenia take in more nicotine per cigarette, and have higher levels of nicotine dependence (Strand & Nybäck, 2005; Williams et al., 2005). Standard dose nicotine replacement may not have provided adequate relief of nicotine craving and withdrawal and future studies should examine more aggressive nicotine dosing regimens. Also of note, we allowed subjects to remain on patch treatment even if they continued to smoke. A recent review of 11 studies that included blood nicotine concentrations concluded that concurrent use of nicotine replacement medication and cigarette smoking appears to be safe (Fagerström & Hughes, 2002). Using nicotine replacement medication concurrently with smoking may reduce smoking, and increase motivation to stop (Fagerström, Tejding, Westin, Lunell, 1997). No one in the study had clinically significant nicotine toxicity even with concomitant smoking.

To date only 5 studies of nicotine replacement therapy (NRT) have been conducted for smoking cessation in schizophrenia or schizoaffective disorder and all have been studies of nicotine patch; there are no published placebo controlled studies of any of the other FDA approved products (nicotine gum, inhaler, nasal spray or lozenge) (Addington et al., 1998; Baker et al., 2006; George et al., 2000; Williams, et al., 2007; Ziedonis & George, 1997). A placebo-controlled trial of bupropion (BUP) combined with nicotine patch (NP) for smoking cessation in schizophrenia resulted in greater continuous (CA) abstinence (28%) than the placebo + NP group (3%) at 8 weeks after the TQD (George, et al., 2008). The lower rates observed with the nicotine patch in the George study may be due to the briefer nature of the counseling.

Failure to stop smoking on the targeted quit date was not a criterion for removing a subject from the study and consistent with other studies of schizophrenia. Subjects continued to receive their behavioral therapy treatment even without having quit on quit date, and the treatment focused on enhancing motivation to pick a new quit date or to just continue to attend sessions and discuss their tobacco use. Of note, we observed reductions in smoking in individuals who were not able to achieve complete abstinence. Reductions in smoking were observed in both measures of cigarettes per day and expired carbon monoxide measures. One study has shown that smokers with schizophrenia who significantly reduced their smoking went on to subsequent quitting and some have argued that this may be an alternative harm reduction strategy for this population (Evins et al., 2004; McChargue, Gulliver, Hitsman, 2002).

Limitations of the study included that clinicians in the trial were trained in and delivered both TANS and MM treatments. Although we provided close supervision and monitored treatment adherence through audiotapes and ongoing supervision, therapeutic alliance, among other factors, could have blurred the distinction between groups. In addition, there might have been a need for increased training on motivational interviewing to maximize its effects prior to the TQD. The TANS treatment approach did include use of feedback reports

and a motivational interviewing style which incorporated the “spirit” of motivational interviewing (MI); however therapists were not given extensive training in MI. Although the study clinicians were skilled community therapists, this was their first time providing individual tobacco dependence treatment. Trainings were detailed in delivery of tobacco and nicotine specific information and assumed skill in general psychotherapy skills. For the TANS approach, we believe this is the first time that social skills training were adapted for individual treatment instead of the traditional group treatment approach. Group interaction, modeling and feedback may enhance and facilitate role playing and other aspects of skills training in a more optimal way. Another possible limitation was the important role of nicotine replacement medication minimizing behavioral therapy differences.

Findings from this study support that mental health clinicians can be trained to effectively help smokers with schizophrenia or schizoaffective disorder to maintain tobacco abstinence using individual counseling and nicotine replacement medication. The mental health treatment system has not traditionally included smoking cessation in its treatment options which has created barriers that must now be overcome. Psychiatric patients receive treatment in a wide range of treatment intensities (inpatient, residential, partial hospitalization, intensive outpatient, outpatient, and outreach) and this allows for different opportunities to adapt and integrate smoking cessation treatment. This study demonstrates that both the TANS and MM approaches can be integrated into the two standard individual mental health treatment session formats in the real world (20 minute versus 45 minute). Another possibility is that subjects suffered from “treatment fatigue” in the TANS group from receiving the more frequent and lengthier sessions. Nine targeted twenty minute sessions of MM counseling resulted in reasonable rates of continuous abstinence and holds promise for a feasible real-world approach for the treatment of tobacco dependence in mental health settings, as this treatment is more cost-effective for programs to implement. More research is needed to further improve treatment outcomes for this high risk group. Future studies might consider testing individual vs. group treatment approaches in an effort to further improve treatment outcomes for this difficult to treat population. Also there is a need for longer-term follow-up to see if the initial success seen with these approaches is sustainable over time.

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Table 1

Baseline characteristics (N=87)

	TANS (n=45)	MM (n=42)	p-value
	Mean (SD)	Mean (SD)	
Cigarettes per day	22.5 (13.9)	22.5 (13.1)	0.984
Baseline CO (ppm)	16.6 (11.0)	21.3 (11.1)	0.049
FTND	5.87 (2.00)	5.83 (1.83)	0.936
Years smoked	24.2 (12.6)	27.7 (11.5)	0.177
Age of first smoking	14.6 (3.9)	13.4 (4.1)	0.188
Age	43.5(12.1)	47.1 (10.5)	0.133
Race/Ethnicity	Count (%)	Count (%)	0.416
African-American	8 (17.8)	11 (26.2)	
Caucasian	29 (64.4)	28 (66.7)	
Hispanic	2 (4.4)	1 (2.4)	
Asian	3 (6.7)	0 (0.0)	
Other	3 (6.7)	2 (4.8)	
Gender	Count (%)	Count (%)	0.806
Male	29 (64.4)	26 (61.9)	
Female	16 (35.6)	16 (38.1)	
Marital Status	Count (%)	Count (%)	0.741
Never married	30 (66.7)	26(61.9)	
Married	3 (6.7)	5 (11.9)	
Separated	4 (8.9)	2 (4.8)	
Divorced	6 (13.3)	8 (19.0)	
Other/Unknown	2 (4.4)	1 (2.4)	
Education	Count (%)	Count (%)	0.268
No HS	7 (15.6)	11 (26.2)	
HS/GED	25 (55.6)	25 (59.5)	
Associate's degree	4 (8.9)	1 (2.4)	
Bachelor's degree	8 (17.8)	3 (7.1)	
Other	1 (2.2)	2 (4.8)	
Employment Status	Count (%)	Count (%)	0.235
Unemployed	36 (80.0)	36 (85.7)	
Employed part-time	6 (13.3)	7 (14.3)	
Employed full-time	3 (6.7)	0 (0.0)	
Current Smoking Goal ^a	1.22 (0.67)	1.12 (0.45)	0.406
Past quit attempts	2.78 (2.62)	3.43 (2.84)	0.269
Disease or illness caused or aggravated by smoking	Count (%)	Count (%)	0.534
No	26 (57.8)	27 (50.9)	
Yes	19 (42.2)	15 (35.7)	
Diagnosis	Count (%)	Count (%)	0.561
Schizophrenia	24 (53.3)	25 (59.5)	

	TANS (n=45)	MM (n=42)	<i>p-value</i>
	Mean (SD)	Mean (SD)	
Schizoaffective disorder	21 (46.7)	17 (40.5)	
Beck Depression Inventory	17.09 (12.23)	13.67 (10.35)	0.164
PANAS Score	15.53 (11.11)	12.95 (10.77)	0.275
Alcohol and Other Substance Use Last 30 days			
No	32 (71.1)	29 (69.0)	0.834
Yes	13 (28.9)	13 (31.0)	
Lifetime History of Treatment for Alcohol or Other Substance Use			
No	28 (62.2)	22 (52.4)	0.354
Yes	17 (37.8)	20 (47.6)	
PANSS Positive	14.58 (5.22)	13.67 (4.88)	0.404
PANSS Negative	10.53 (3.67)	11.26 (4.50)	0.409
Importance	9.44 (1.14)	9.31 (1.28)	0.604
Confidence	6.91 (2.30)	7.17 (2.81)	0.643
Readiness	7.56 (2.51)	7.88 (2.43)	0.530
CPZ Equivalence	295.83 (206.55)	395.79 (287.42)	0.101

^a 1=to quit and stay off forever; 2=to not smoke for a limited time; 3=to be able to control how much I smoke; 4=to quit someday but not now; 5=to continue to smoke.

Table 2

Continuous abstinence rate by percent session attendance*

Treatment Group	Session Attendance in Thirds	Equivalent Number of Sessions	Number Who Attended	Percentage	OR	95% CI
TANS N=45	<1/3	1-8	14	0(0/14)	b	-
	1/3-2/3	9-16	13	8%(1/13)	1.71	0.09-3.22
	>2/3	17-24	18	30%(6/18)	0.64	0.18-2.17
MM N=42	<1/3	1-3	4	0(0/4)	b	-
	1/3-2/3	4-6	15	7%(1/15)	0.583	0.31-10.86
	>2/3	7-9	23	43%(10/23)	1.56	.46-5.31

* Continuous Abstinence Rate at 12 Weeks for both groups was 21% (18/87), OR 1.0

b=Undefined confidence interval