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Treating Tobacco Dependence at the Intersection of Diversity, Poverty, and Mental Illness: A Randomized Feasibility and Replication Trial

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Abstract

Introduction: In an ethnically-diverse, uninsured psychiatric sample with co-occurring drug/alcohol addiction, we evaluated the feasibility and reproducibility of a tobacco treatment intervention. The intervention previously demonstrated efficacy in insured psychiatric and nonpsychiatric samples with 20.0%–25.0% abstinence at 18 months.

Methods: Daily smokers, recruited in 2009–2010 from psychiatric units at an urban public hospital, were randomized to usual care (on-unit nicotine replacement plus quit advice) or intervention, which added a Transtheoretical-model tailored, computer-assisted intervention, stage-matched manual, brief counseling, and 10-week post-hospitalization nicotine replacement.

Results: The sample (N = 100, 69% recruitment rate, age M = 40) was 56% racial/ethnic minority, 65% male, 79% unemployed, and 48% unstably housed, diagnosed with unipolar (54%) and bipolar (14%) depression and psychotic disorders (46%); 77% reported past-month illicit drug use. Prior to hospitalization, participants averaged 19 (SD = 11) cigarettes/day for 23 (SD = 13) years; 80% smoked within 30 minutes of awakening; 25% were preparing to quit. Encouraging and comparable to effects in the general population, 7-day point prevalence abstinence for intervention versus control was 12.5% versus 7.3% at 3 months, 17.5% versus 8.5% at 6 months, and 26.2% versus 16.7% at 12 months. Retention exceeded 80% over 12 months. The odds of abstinence increased over time, predicted by higher self-efficacy, greater perceived social status, and diagnosis of psychotic disorder compared to unipolar depression.

Conclusions: Findings indicate uninsured smokers with serious mental illness can engage in tobacco treatment research with quit rates comparable to the general population. A larger investigation is warranted. Inclusion of diverse smokers with mental illness in clinical trials is supported and encouraged.

Introduction

Individuals diagnosed with psychiatric disorders have higher prevalence of cigarette smoking (36% vs. 21%); greater nicotine dependence; and in epidemiologic studies, less likelihood of quitting compared to smokers without mental illness.[1–3] Smokers with mental illness and addictive disorders are estimated to consume 44%–46% of cigarettes smoked in the United States,[4,5] and account for 200 000 of the 480 000 tobacco-related premature deaths in the United

States annually.[6,7] The average life expectancy for individuals with serious mental illness is 25 years shorter than the general population, primarily due to tobacco-related diseases, such as cardiovascular disease, lung disease, and many types of cancer.[8] Tobacco addiction also is costly; in one study of smokers with schizophrenia, estimated at 27% of their median income.[9]

Tobacco Clinical Practice Guidelines recommend providing cessation treatment to all smokers.[10] The Joint Commission banned smoking in US hospitals in 1993,[11] and the American Psychiatric Association identifies psychiatric hospitalizations as an ideal opportunity to treat tobacco dependence,[12] yet treatment of tobacco in psychiatry is not regular practice. Many mental health professionals think smokers with mental illness do not want to quit and cannot quit.[13] Further, tobacco is believed to be a form of self-medication for these individuals, with fears that banning smoking in psychiatric units would worsen symptoms and increase behavioral problems, though published reviews suggest otherwise.[14]

Smokers with mental illness are as motivated to quit smoking as the general population[15]; among hospitalized smokers with mental illness, 65% were interested in quitting.[16] Tobacco treatment randomized trials have had significant effects on long-term abstinence and have found that quitting smoking does not worsen clinical symptoms of unipolar depression, bipolar disorder, posttraumatic stress disorder, or schizophrenia.[17–21] Further, treatment of tobacco dependence was associated with a decreased likelihood of rehospitalization.[22] A review of cessation treatments for outpatients with mental illness concluded that for depressed smokers, cognitive-behavioral and nicotine replacement therapy (NRT) doubled cessation rates and reduced depressive symptoms.[23] Notably, the combination of NRT and buproprion resulted in more abstinence than NRT alone among smokers with schizophrenia.[24] Together the evidence suggests that pharmacotherapy and psychological counseling are effective in helping people with mental illness to quit smoking.

Increasingly, psychiatric hospitals are adopting smoking bans.[25] Notably, without treatment, the majority of hospitalized psychiatric patients return to smoking shortly after discharge from a smoke-free unit.[14,16] While the hospital setting provides a unique opportunity to initiate tobacco dependence treatment among a group of vulnerable, underserved smokers, the inpatient psychiatric setting has rarely been the focus of cessation trials. Only two published randomized trials have examined the efficacy of tobacco dependence treatments among adults[22] or adolescents[26] hospitalized in inpatient psychiatry. Both trials enrolled smokers regardless of intention to quit and provided counseling combined with post-hospitalization NRT relative to brief advice. The adult trial utilized a Transtheoretical model (TTM)-tailored, computer-assisted intervention on unit and repeated at 3- and 6-month follow-up, combined with a stage-matched manual and brief individual on-unit counseling. Quit rates significantly increased over time and differed by condition with 20% of treatment and 8% of usual care participants abstinent at 18-month follow-up.[22] Further, abstinence rates were comparable to prior evaluations of the treatment approach among depressed outpatients (25% quit at 18 months) and participants from the general population (22%–25% quit at 18 months).[18,27] The adolescent trial utilized motivational interviewing and demonstrated an increase in self-efficacy and intentions to quit, but no difference by group in abstinence.[26] The trials were conducted in hospitals affiliated with academic medical centers with participants who were largely insured and non-Hispanic Caucasian. Acceptability and efficacy of tobacco treatment interventions with more diverse and representative samples still requires evaluation.

This translational randomized clinical trial had the primary aim of testing the TTM-tailored, computer-assisted intervention with stage-matched manual, brief on-unit counseling, and post-hospitalization NRT with a racially/ethnically diverse sample of uninsured smokers with serious mental illness recruited from a large, urban, public hospital. This feasibility and replication trial was not powered to detect significant differences due to budgetary and time constraints of the funding award. The primary aim was to examine treatment group differences in abstinence rates over 12 months time. We hypothesized that the treatment group would have greater 7-day point prevalence tobacco abstinence over 12 months after hospitalization compared with the usual care group. The secondary aim was to characterize baseline sociodemographic, clinical, and tobacco-related predictors of abstinence. Specifically, we hypothesized that lower socioeconomic status, unstable housing, greater nicotine dependence, reduced motivation to quit, poorer mental health, and more racial discrimination experiences would predict less smoking abstinence over the 12-month period. Lastly, we examined predictors of acute psychiatric service use (ie, psychiatric rehospitalization or treatment in emergency services), over the 12-month study, including study condition, tobacco abstinence, and the sociodemographic, clinical, and tobacco measures of interest.

Methods

Setting

We recruited adult smokers from three smoke-free psychiatric units (one non-acute and two acute units) at San Francisco General Hospital (SFGH) between April 2009 and April 2010. SFGH went 100% smoke-free on July 1, 2008. SFGH is the largest public acute care hospital in San Francisco County, primarily serving the city's uninsured, indigent, and unhoused.

Study Design

The SFGH two-arm randomized clinical trial was an extension and replication of a larger trial (N = 224) conducted at the Langley-Porter Psychiatric Institute[22] that also enrolled smokers regardless of intention to quit and compared enhanced usual care with a TTM-tailored intervention. The http://ClinicalTrials.gov identifier was NCT00136812. SFGH's usual care assessed tobacco use and provided NRT for tobacco users while hospitalized to manage nicotine withdrawal. For the trial, the usual care condition was enhanced by study staff advising smokers to quit, providing a quit smoking pamphlet,[28] and offering referrals post-hospitalization.

The intervention condition added a TTM-tailored computer-delivered intervention with printed report, a stage-matched treatment manual, on-unit individual cessation counseling, and the availability of 10 weeks of NRT post-hospitalization up to the 6-month follow-up. Cessation counseling, provided by study staff, focused on motivational enhancement, managing temptations, decisional balance, and the processes of change in a 15–30 minute session. The individualized report directed participants to relevant exercises in the manual; materials were written at a sixth-grade reading level. Post-hospitalization intervention contacts at 3 and 6 months repeated the computer intervention, which remembered participants' earlier responses and provided ipsative feedback on how they changed over time, recommending next steps toward quitting smoking and maintaining abstinence. To prevent loss or misuse, the study-NRT was delivered in two installments (4- and 6-week increments). We previously reported on acceptability of the intervention evaluated

with an insured psychiatric sample.[29] For the current study, treatment adaptations included use of more ethnically diverse and urban images in the computer program and treatment manual, greater reference to menthol tobacco use, the tobacco industry's marketing of cigarettes to Blacks and lower income smokers, and greater outreach in the field to ensure completion of post-hospitalization treatment sessions.[30]

We randomly assigned participants to the treatment or enhanced usual care arm through a computer-generated random assignment program stratified by baseline cigarettes per day (>15) and stage of change, two variables predictive of quitting smoking and addressed by the intervention.[27,31] Research staff was blinded to the randomization schedule. The research protocol was approved by the Committee for Human Research at the University of California, San Francisco and by the SFGH administration.

Participants

Research staff used the medical record to identify potentially eligible patients, and then clinical staff asked the patients if they would like to hear about a smoking study; those interested were introduced to research staff who provided a greater description of the study and assessed eligibility for the trial. Inclusion criteria were smoking at least five cigarettes daily prior to hospitalization, being aged 18 years or older, and fluency in written and spoken English. We excluded patients physically threatening to staff or sedated to the point of being non-communicative if these symptoms did not resolve sufficiently during hospitalization or contraindicated for NRT use. Research staff reviewed the consent form with participants and assessed understanding of the purpose and potential risks and benefits of participation using a brief capacity screening instrument.[32] Participant compensation was $10 for the baseline assessment, $20 per in-person follow-up ($10 if by phone/mail/email), plus a $20 bonus for completing all assessments ($120 maximum).

Measures

Descriptive Measures

We assessed age, gender, race/ethnicity, education, annual income, housing stability, employment status, and marital status. The MacArthur Scales of Subjective Social Status[33] had participants place an "X" on the rungs of two graphical ladders to reflect their perceived social standing in their self-defined community (SSS-community) and in the United States (SSS-US) more broadly, each rated from 1–10. Tobacco characteristics assessed were cigarettes per day; the Fagerström Test of Cigarette Dependence,[34,35] including time to first cigarette; Smoking Stage of Change, categorized as precontemplation (no intention to quit in the next 6 months), contemplation (intention to quit in the next 6 months), and preparation (intention to quit in the next 30 days with a past year 24-hour quit attempt)[36]; the Thoughts about Abstinence scale assessed desire to quit, anticipated success with quitting, and perceived difficulty quitting (three single items rated on 10-point scales).[37] We also assessed all forms of tobacco use including cigars and smokeless, menthol use, years of smoking, and cessation advice from mental and general health providers in the past year.

Measures of mental health status and substance use included: the Center for Epidemiologic Studies Depression Scale (CESD-10)[38]; the Behavior and Symptom Identification Scale (BASIS-24)[39]; the Health Status Survey Short Form (SF12) with Physical and Mental Health Composite Scores[40]; the Alcohol Use Disorders Identification Test[41]; the Drug Abuse Screening Test (DAST-10)[42]; and the Addiction Severity Index items of past 30-day substance use.[43] Clinical diagnoses and duration of the psychiatric hospitalization were obtained from the medical record. Number of prior hospitalizations also was assessed. Two measures of race-related stress were administered.[44] The Major Experiences of Discrimination yielded a count of the number of nine major experiences of unfair treatment over one's lifetime related to issues such as employment, education, and housing. The Everyday Discrimination Scale assessed exposure to 10 chronic experiences of unfair treatment in the past month such as being treated with less courtesy and respect or receiving poorer service than others in stores. Given the patient population, we added 3 items to the everyday measure: Did you receive poorer service when getting mental healthcare or medical care (2 questions) and were you denied mental health care? Cronbach's alpha for the 22 items was 0.90, and a single discrimination frequency score was tabulated.

Outcome Measures

Feasibility of the trial was assessed by sample recruitment and retention rates. The primary tobacco outcome was 7-day point prevalence abstinence from any form of tobacco (including smokeless) assessed and verified at the 3-, 6-, and 12-month follow-ups.[45] Those reporting no tobacco use completed biochemical verification with an expired air carbon monoxide (CO) sample analyzed by a Bedfont Smokerlyzer. CO of 10 parts per million or less verified abstinence.[46] For participants lost to follow-up or unable to attend in person to confirm nonsmoking status, we called their collateral contacts (eg, friends, family, case managers) provided at baseline and asked about participants' tobacco use in the past 7 days. Prior research with smokers with alcohol problems has compared collateral informant reports and CO confirmation, demonstrating validity.[47] The clinical outcome of interest was use of acute psychiatric services, defined as either psychiatric treatment in emergency services or rehospitalization, assessed by participant self-report at each follow-up and via the hospital's electronic medical record.[48]

Data Analysis

Descriptive statistics (means, frequencies) summarized sample characteristics overall and by group with analysis of variance and Pearson's chi-square tests for group differences. Sample retention at 12 months was examined, testing for differences by treatment condition and baseline descriptive characteristics. To test the primary hypothesis, we estimated and tested a generalized estimating equation model with the logit link function (PROC GENMOD in SAS version 9.2).[49] The model examined abstinence versus smoking status at the 3- through 12-month follow-ups by condition and accounted for dependence of responses within individuals attributable to repeated measures. The independent variables were intervention versus usual care condition plus variables that differed by condition at baseline or predicted attrition. The dependent variable was 7-day point prevalence abstinence which was modeled over time at 3, 6, and 12 months.

To test the secondary hypothesis, model building proceeded in two steps. In univariate models, we first examined baseline sociodemographic, tobacco-related, and clinical characteristics predicting tobacco abstinence over the 12-month study, and then variables associated at $P < .05$ were entered into a final generalized estimating equation-based multivariate logistic model. For the clinical outcome of acute psychiatric care services use at any point during the 12-month trial, we estimated and tested a logistic regression model with independent variables of treatment condition, abstinence status,

and covariates identified as relevant to psychiatric hospitalization in the literature.

Results

A total of 145 adult smokers were identified as study eligible from the medical record, of whom, 40 declined participation, five did not pass the capacity screener after two trials, and 100 provided informed consent, for a 69% recruitment rate with 49 participants randomized to the intervention arm and 51 to the enhanced usual care arm (Figure 1).

The mean age of the sample was 39.5 years (*SD* = 11.3); 65% were men; 56% were racial/ethnic minorities; 20.0% identified as lesbian, gay, bisexual, or transgender; and 15% were foreign born (Table 1). Just over half (52%) reported living in their current residence at least 6 months; 19% were unhoused; and 78% had a substance use disorder diagnosis reported in the medical record. Prior to hospitalization, participants smoked an average of 19.3 cigarettes per day (*SD* = 12.2) for an average of 23.1 years (*SD* = 12.7), 80% smoked their first cigarette within 30 minutes of waking, and 53% smoked menthols; 33% were in precontemplation, 42% in contemplation, and 25% in preparation for quitting smoking.

Participants were hospitalized for danger to self (73%), danger to others (14%), and grave disability (13%); 53% were hospitalized for more than a week. In the 30 days before hospitalization, 77% used illicit drugs, 67% consumed alcohol, and 55% used both illicit drugs and alcohol. The majority had Medicare or Medicaid (66%) as their insurance carrier.

In terms of racial discrimination experiences, 36% reported none, 32% reported 1–3, and 26% reported 4 or more. CESD-10 scores were significantly higher among participants who experienced racial discrimination (*M* = 17.7, *SD* = 7.0) than those who did not (*M* = 13.7, *SD* = 9.0; *F*[1,92] = 5.84, *P* = .02). Discrimination experiences were not associated with heavier smoking or nicotine dependence.

Treatment Delivery and Study Retention

All intervention participants completed the initial computer and counseling session during their acute stay. After hospitalization, 65% and 53% completed their second and third intervention contacts, respectively. Three intervention participants did not complete

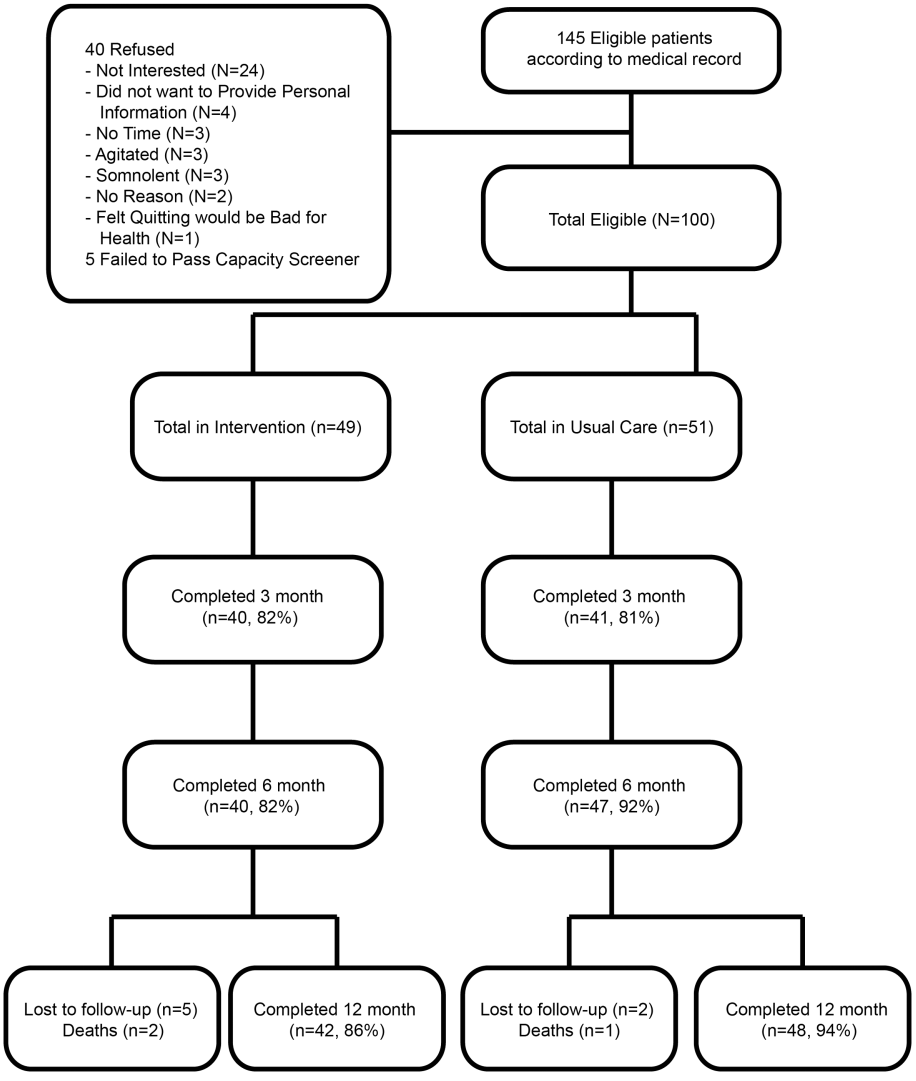

Figure 1. Screening and enrollment of study participants.

Table 1. Sociodemographic, Tobacco, and Clinical Characteristics of a Sample of Psychiatric Inpatients in a Randomized Controlled Trial of a Smoking Cessation Intervention: San Francisco, CA, Recruited April 2009–April 2010

Characteristic	Full sample (n = 100), mean ± *SD* or number
Sociodemographic characteristics	
Age, years	39.5 ± 11.3
Gender	
Male	65
Female	32
Transgender	3
Race/ethnicity	
Caucasian	44
Black	27
Hispanic	9
Asian American/Pacific Islander	11
Multiracial/native American/other	9
Marital status	
Married/cohabiting	10
Divorced, separated, widowed	28
Single, never married	62
Annual individual income, $	
<$10 000	67
≥$10 000	33
Housing stability	
Unstably housed	48
Stably housed for ≥6 months	52
Education, years	12.8 ± 2.5
Employment status	
Unemployed	79
Employed	12
Retired/student/homemaker	9
MacArthur scale of subjective social status	
Social status in community	5.2 ± 2.9
Social status in United States	4.4 ± 2.8
Tobacco characteristics	
Usual cigarettes per day	19.3 ± 12.2
Menthol use	53
FTCD total score	5.2 ± 2.3
Time to first cigarette of the day	
Within 30 min	80
After 30 min	20
Years of smoking	23.1 ± 12.7
Thoughts about abstinence	
Desire to stop	5.9 ± 3.2
Expected success with quitting	5.7 ± 3.0
Difficulty staying abstinent	6.9 ± 3.1
Stage of change	
Precontemplation	33
Contemplation	42
Preparation	25
Quit attempt in past year (≥24 h)	44
Cessation advice from mental health provider in the past year	45
Cessation advice from non-mental health provider in the past year	46
Clinical characteristics	
Reason for hospitalization	
Danger to self	73
Danger to others	14
Grave disability[a]	13
Length of hospital stay, days	
2–7 days	47
8–13 days	30
2 weeks or longer	23
CESD-10 score[b]	16.0 ± 8.1
Diagnosis in medical record	
Unipolar depression	52
Bipolar disorder	15

Table 1. *Continued*

Characteristic	Full sample (n = 100), mean ± *SD* or number
Psychotic disorder	29
No diagnosis reported	4
BASIS-24 summary scale[c]	1.9 ± 0.8
AUDIT total score[d]	8.7 ± 9.8
DAST-10 total score[e]	4.1 ± 3.6
SF-12[f]	
Physical component summary	46.4 ± 11.9
Mental component summary	33.5 ± 14.7
Previous psychiatric hospitalization	
1–5	64
6 or more	33

Subjective social status refers to the MacArthur Scale of Subjective Social Status[33]; FTCD = Fagerström Test of Cigarette Dependence; range = 0–10; 0–2 = very low dependence, 3–4 = low dependence, 5 = medium dependence, 6–7 = high dependence, 8–10 = very high dependence[34,35]; AUDIT = Alcohol Use Disorders Identification Test[41]; BASIS = Behavior and Symptom Identification Scale[39]; CESD = Center for Epidemiologic Studies Depression Scale.[38]

[a]A condition, as a result of a mental disorder, that renders a person unable to take care of basic needs or obtain food, clothing, and shelter.

[b]Range = 0–30; ≥11 indicates significant depressive symptoms.

[c]Range = 0–4; higher indicates more severe symptoms.

[d]Range = 0–40; ≥8 indicates hazardous and harmful drinking.

[e]Range = 0–10; ≥3 indicates moderate drug problems.

[f]Range = 0–100, national average = 50, *SD* = 10; lower scores indicate worse mental and physical health.

their follow-up computer contacts due to incarceration. In total, 16 participants were incarcerated during the course of the study. Post-hospitalization, study-provided NRT was requested and distributed to 28 participants (57% of the treatment group); 25% of intervention participants received the full 10-week regimen of study patches. Abstinence rates did not differ based on distribution of study-NRT.

More than 80% of follow-up assessments were completed at all time points, with retention rates increasing over the course of the trial due to greater outreach efforts.[30] Retention was 86% for the intervention group and 94% for the usual care group at the 12-month follow-up, a nonsignificant difference (Figure 1). No measured characteristics predicted 12-month retention. Three participants died during the trial, all by suicide.

Abstinence Status

Verified 7-day point prevalence abstinence rates were 7.3% for usual care and 12.5% for intervention at the 3-month follow-up, 8.5% and 17.5% at 6 months, and 16.7% and 26.2% at 12 months (Figure 2). Modeling abstinence over 12 months revealed significant differences in quitting over time (generalized estimating equation model: *OR* = 1.11; 95% CI = 1.02, 1.20; *P* = .02), with the differences by treatment condition not statistically significant (*OR* = 1.80; 95% CI = 0.74, 4.38; *P* = .19; Figure 2). Overall, collateral reports were relied upon to verify smoking status for 6%, 6%, and 9% of participants at the 3-, 6-, and 12-month assessments, respectively. Among participants coded as abstinent, expired CO confirmation was obtained on the majority with collateral reports used for 12.5%, 18.2%, and 31.6% of participants at the 3-, 6-, and 12-month assessments, respectively.

For comparison with the literature, we coded participants lost to follow-up as smoking, excluding deceased participants. Verified 7-day point prevalence abstinence rates were 6.0% for usual care and 10.4% for intervention participants at the 3-month follow-up, 8.0% and 14.9% at 6 months, and 16.0% and 23.4% at 12 months.

Predictors of Condition and Abstinence

Next, we examined potential covariates of treatment effects to elucidate predictors of abstinence in this clinical sample. In univariate models, baseline measures of social standing (SSS-community, SSS-US), quitting self-efficacy (Thoughts about Abstinence desire, success, anticipated difficulty), physical health (SF12), substance use (DAST-10), and psychiatric diagnosis predicted abstinence over time (all *P* values < .05). Gender, age, race/ethnicity, marital status, income, employment, cigarettes per day, menthol use, years of smoking, stage of change, past quit attempts, length of hospitalization, reason for hospitalization, and scores on the Fagerström Test of Cigarette Dependence, CESD-10 and DAST did not predict abstinence. Despite randomization, the two groups differed at baseline on education level, housing stability, alcohol use (Alcohol Use Disorders Identification Test), and BASIS-24 summary score (all *P* values < .05). SSS-community, which highly correlated with SSS-US (r = 0.70, *P* < .001), was excluded from the model. The remaining 11 variables were entered into a multivariate analysis (Table 2). Significant variables in the final model were time, SSS-US, Thoughts about Abstinence desire and success, and psychiatric diagnosis (all *P* values < .05). The odds of abstinence increased over time, predicted by greater baseline desire and self-efficacy to quit smoking, greater perceived social status in the United States, and with having a psychotic disorder diagnosis compared to unipolar depression.

Psychiatric Rehospitalization

Among the sample, 28 participants in usual care (55%) and 28 in intervention (57%) were rehospitalized or seen in emergency services for psychiatric care over the 12 months of follow-up. Use of acute psychiatric services during the 12-month study was unrelated to any of the modeled variables, including abstinence status, study condition, gender, ethnicity, education, prior hospitalization and severity of psychiatric symptoms at baseline, psychiatric diagnosis, and stability of living situation.

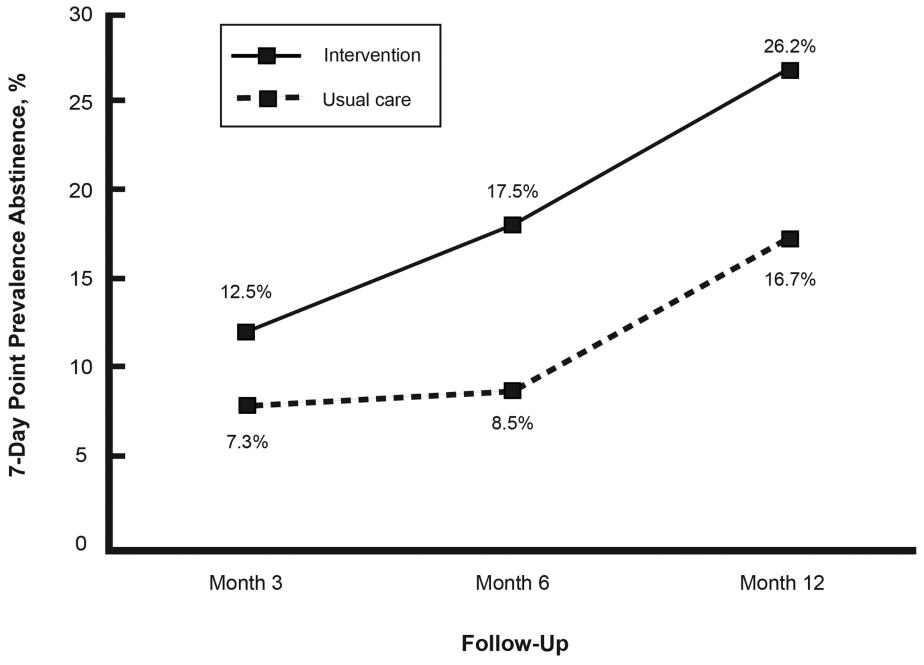

Figure 2. Verified point prevalence abstinence rates by treatment condition and time in a randomized controlled trial of a smoking cessation intervention for psychiatric inpatients: San Francisco, CA, Recruited April 2009–April 2010.

Table 2. Multivariate Model Predicting Tobacco Abstinence Over a 12-Month Study Period in a Randomized, Controlled Trial of a Smoking Cessation Intervention Among Psychiatric Inpatients: San Francisco, CA, Recruited April 2009–April 2010

Variable	*OR* (95% CI)	*P*
Condition (ref: usual care)	1.76 (0.69, 4.48)	.24
Time	1.16 (1.04, 1.29)	.007
Education, years	0.90 (0.74, 1.09)	.28
Housing stability	0.77 (0.31, 1.91	.58
Social status in United States	1.25 (1.04, 1.50)	.02
Desire to quit	1.28 (1.06, 1.55)	.01
Expected success with quitting	1.26 (1.06, 1.50)	.007
Perceived difficulty staying quit	0.92 (0.79, 1.06)	.25
SF-12 Physical component summary	1.03 (0.99, 1.09)	.17
BASIS-24 summary scale	0.89 (0.38, 2.06)	.78
Psychiatric diagnosis		
Unipolar depression (ref)	1.00	
Bipolar depression	0.73 (0.12, 4.53)	.73
Psychotic disorder	5.16 (1.76, 15.07)	.03

CI = confidence interval; *OR* = odds ratio. The sample size was *N* = 100. Figures will be uploaded for peer-review as a.TIF file format and according to requirements detailed in the instructions to authors document.

Discussion

High levels of recruitment and retention support the feasibility of treating tobacco addiction among smokers in public psychiatric hospitals. In terms of replication, we found a significant increase in abstinence over time, with higher quit rates in the intervention versus enhanced usual care group. Consistent with our prior work in psychiatric samples and research with smokers in the general population, the increase in abstinence over time is characteristic of stage-tailored interventions, whereby smokers not initially intending to quit are supported through the cessation process over time.[18,22,27,50,51] The pattern of increase in abstinence over time in these "cessation-induction trials"[45] is in contrast to characteristic relapse curves of traditional action-oriented treatment approaches.[52] Repeated intervention contacts provide the opportunity to engage participants not initially ready to quit. Further, the current study's 12-month abstinence rate of 26% was comparable to prior investigations of similar TTM-based approaches with inpatient psychiatric smokers, depressed outpatient smokers, and studies with smokers without mental illness.[18,22,27]

Designed as a demonstration/feasibility project, a study with this relatively small sample size would have 80% power to detect an odds ratio of 2.67 for a continuous predictor such as the CESD score and an odds ratio of 4.60 for a binary predictor such as treatment group or a covariate like bipolar disorder status.[53] The differences in percent abstinent at the 3-, 6-, and 12-month assessments translate to number needed to treat of 20, 11, and 10.5, respectively. Lack of a statistically significant treatment group difference in the current trial is likely due in part to the short duration of follow-up, small sample size, and quit rate of 16.7% in the usual care group. In the parent trial, only 7.7% of participants in the usual care arm were abstinent at 18 months.[22] A vulnerable, at-risk population, the enhanced usual care group in the current study was supported by study staff to obtain NRT while hospitalized and was provided with community cessation referrals.

In examining correlates of abstinence, we found partial support for the second hypothesis in that patients at baseline reporting greater perceived social status in the United States, greater desire to quit, and greater anticipated success with quitting were more likely to achieve abstinence during the trial. The relationship between expected success with quitting and abstinence is consistent with our earlier findings,[22] and Reitzel and colleagues[54] have found perceived social status in the United States to predict abstinence among unhoused smokers and racially/ethnically diverse smokers seeking treatment.[55] An unexpected finding was the higher likelihood of abstinence among participants with a psychotic disorder compared

to unipolar depression. Our earlier study found no difference in abstinence by diagnosis,[22] and few investigations have included diagnostically heterogeneous samples allowing for comparison by type of mental illness. Unrelated to abstinence were measures of income, employment status, housing stability, nicotine dependence, mental health, and racial discrimination. Prior studies have supported the link between discrimination experiences, nicotine dependence and heavier smoking,[56–58] and Kendzor and colleagues[59] found a greater number of racial discrimination experiences predicted lower tobacco abstinence among treatment seeking Latinos; however, Fagerström Test of Cigarette Dependence and cigarettes per day were not associated with discrimination in our sample.

The likelihood of acute psychiatric service use did not differ by condition or any other modeled variable and was greater in the current sample (56%) than in our study of insured smokers recruited from an academic psychiatric hospital (47%) over an 18-month follow-up window. Close to study start, budget shortfalls in the San Francisco community mental health system placed considerable pressure on SFGH psychiatry to reduce length of psychiatric visits and re-direct patients with chronic mental illness to more affordable outpatient community mental health services.[60] The system changes likely resulted in increased use of acute psychiatric services during the study period, and diversion of chronic cases, making it difficult to identify significant demographic and clinical correlates.

The study was limited to a 12-month follow-up. With additional support over time, abstinence rates may have continued to increase out to 18 months as we have observed in other samples using similar interventions[18,22]; however, it also is possible that relapse could have occurred. Diagnoses were obtained from the medical record instead of validated diagnostic instruments. Participants were recruited from one site and findings may not generalize to other settings. With an urban sample, many of whom were unhoused, we used a CO cut-point of 10 parts per million for abstinence, which may be less than optimal for light smokers.[61] Nevertheless, the promising findings from this study warrant a larger trial among low-income, diverse smokers with serious mental illness with assessment of costs to deliver the intervention and return on investment. Notably, in the parent trial, the intervention, evaluated in inpatient psychiatry, was found to be highly cost-effective with an incremental cost-effectiveness ratio of $428 per quality adjusted life year.[62]

Conclusions

In this translational trial, 100 uninsured, racially/ethnically diverse smokers with serious mental illness were successfully enrolled with high retention over a year's period. Our sample is unique among tobacco treatment trials with representation among the patient population seeking acute mental healthcare through the public health safety net system. Relative to other studies of tobacco treatment in smokers with mental health problems, the current sample had high rates of co-occurring psychiatric and addictive disorders, were actively suicidal at the time of recruitment, and were clinically unstable. Further, participants did not have to want to quit smoking to participate. Notably, participants randomized to a TTM-tailored computer-assisted intervention combined with NRT achieved higher quit rates relative to enhanced usual care. The Affordable Care Act's inclusion of tobacco cessation services should improve access to evidence-based tobacco treatments among previously uninsured individuals.[7] The re-delivery of the intervention at 3 and 6 months fits conceptually with Wagner and colleagues' Chronic Care Model,[63] which emphasizes integrated healthcare systems that build patient confidence and efficacy to manage chronic health conditions. Racially/ethnically diverse smokers with mental illness and low-income represent multiple priority groups with longstanding tobacco-related disparities. This translational trial demonstrates the feasibility of initiating tobacco treatment with a particularly vulnerable group of smokers during a psychiatric hospitalization and replication of treatment effects in a diverse patient group.

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Declaration of Interests

J. J. Prochaska has served as an expert witness against the tobacco companies in lawsuits for which she has received fees for the work and has provided consultation to Pfizer, which makes medications for quitting smoking. N. J. Hickman and K. Delucchi hold no conflicts of interest.

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