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Helping Smokers with Severe Mental Illness who do not want to Quit

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Abstract

Background—People with a severe and persistent mental illness are far more likely to smoke than others. Importantly, a large portion of them would like to quit. Despite this desire, they are less likely to make quit attempts and succeed.

Objective—This study used an RCT to test an intervention designed to increase engagement in cessation treatment, quit attempts, and quitting in smokers who did not want to quit in the next 30 days. It also compared these smokers with those who were motivated to quit in the next 30 days.

Methods—Participants (N=222), smokers with significant mental illness receiving intensive outpatient care from Community Support Programs in Wisconsin who were not interested in quitting in the next 30 days, were randomly assigned to either an intervention group or an attention control group. The intervention, administered during four weekly sessions, included a motivational element, components designed to prepare the smoker for a quit attempt, and pre-quit nicotine patch. Additionally, 48 smokers motivated to quit in the next 30 days served as a comparison group.

Results—Compared to control participants, smokers receiving the intervention were more likely to be abstinent (7 day point prevalence) at the three month follow-up (biochemically verified, intent to treat, 8.5% vs. 1.0%, respectively, $p=.01$). They were also more likely to accept four more quitting preparation sessions (intent to treat, 50.8% vs 29.2%, respectively $p<.001$) but were not

more likely to call a telephone tobacco quit line (intent to treat, 9.3% vs. 5.8%, respectively $p=.45$).

Conclusion/Importance—Brief motivational interventions increased engagement in cessation treatment and abstinence among smokers with significant mental illness.

Keywords

Nicotine Dependence; Severe and Persistent Mental Illness; Quit Smoking; Preparing to Quit; Motivation to Quit

Introduction

The population of people with a mental illness who smoke is both very large and in need of effective smoking cessation interventions. Nationally, almost 45 million American adults experience a mental illness annually including 10.0 million who have a serious mental illness (SAMSHA, 2014). Compared to smokers in the general population, those with a mental illness are more likely to smoke, smoke more cigarettes per day, and smoke more intensively (D'Mello, Bandlamudi, & Colenda, 2001; de Leon & Diaz, 2005; Kelly & McCreddie, 1999; Olincy, Young, & Freedman, 1997; SAMSA, 2013; Schroeder & Morris, 2010). Based on 2012–2014 National Surveys on Drug Use and Health (Lipari & Van Horn, 2017), 33.3% of adults with a mental illness reported that they currently smoke (smoked in the past month) compared to 20.7% of those who do not. Further, the rate of smoking is highest among those with a persistent, severe, disabling mental illness (de Leon & Diaz, 2005; Grant, Hasin, Chou, Stinson, & Dawson, 2004; McClave, McKnight-Eily, Davis, & Dube, 2010; Schroeder & Morris, 2010; Vanable, Carey, Carey, & Maisto, 2003). Based on the National Epidemiological Survey on Alcohol and Related Conditions (NESARC), smoking prevalence among those with psychosis is 50% and over 70% among those with more than four mental health diagnoses with a preponderance of those individuals being heavy smokers (more than 2 packs/day) (Smith, Mazure, & McKee, 2014). Among individuals hospitalized for treatment of a mental illness, 70% smoke (Joshelson & Majrowski, 2006).

Those with a mental illness desire to quit as much as smokers without a mental illness (Szatkowski & McNeill, 2015). Despite this, those with a mental illness are less likely to quit and those with a severe mental illness are particularly less likely to quit (de Leon & Diaz, 2005; McClave et al., 2010; Schroeder & Morris, 2010). Based on the NESARC, the quit rate of smokers without mental illness is 22.3%; for those with any mental illness, 18.4%; and for those with psychosis, 12.5% (Smith et al., 2014). These epidemiological findings exist despite the effectiveness of cessation treatments for this population including medication (varenicline, bupropion, and nicotine replacement), and counseling (Fiore et al., 2008). This low rate of quitting among those with severe mental illness (a mental illness that tends to be chronic and significantly impacts activities of daily living, often resulting in repeated hospitalizations and/or incarcerations) reflects many factors including fewer quit attempts despite a desire to quit (Etter, Mohr, Garin, & Etter, 2004; McClave et al., 2010), and less use of evidence-based treatments during quit attempts (Campion, Checinski, & Nurse, 2008; Etter et al., 2004; Taylor et al., 1993). Thus, there is a great need to find

interventions that motivate smokers with a mental illness to make quit attempts using evidence-based methods. The hospital or intensive outpatient programs are an ideal place to provide these interventions.

A number of interventions have motivated the general population of unmotivated smokers to make a quit attempt. These have included: a variety of counseling strategies such as motivational interviewing (Brown et al., 2003; Butler et al., 1999; Fiore et al., 2008); the 5Rs (Fiore et al., 2008); practice quit attempts (Grimshaw & Stanton, 2006); smoking reduction (Hughes & Carpenter, 2005); and precessation use cessation medicines (Fiore et al., 2008; Hughes & Carpenter, 2005).

However, with a few exceptions, research has not tested these interventions with unmotivated smokers who have severe, persistent mental illness. Steinberg et al. (Steinberg, Ziedonis, Krejci, & Brandon, 2004), compared a single session of motivational interviewing (MI) with psychoeducational counseling among individuals with schizophrenia who did not want immediate cessation treatment. He found MI resulted in more contacts to a tobacco dependence treatment provider and greater attendance at an initial counseling visit. Enhancing the interactivity of the educational intervention increased quit attempts and follow-ups on a referral for tobacco dependence treatment but did not increase abstinence at 1-month follow-up for smokers, who did not plan to quit in the next 30 days, receiving motivational interviewing compared to those receiving the educational intervention (Steinberg, Williams, Stahl, Budsock, & Cooperman, 2016). Brunette et al. (Brunette et al., 2013; Brunette et al., 2011) had smokers with a severe mental illness use an electronic decision support tool that addressed risks of smoking, benefits of quitting, and evidence-based treatments. Study participants were told that they would not have to change their smoking habits in order to be part of the study (Brunette, 2011) or excluded those that had used smoking cessation treatment in the past month as indicative of motivation to quit (Brunette, 2013). Participants using the decision support tool showed greater motivation to quit, such as meeting with a cessation specialist or initiating a quit attempt. Nine percent of participants had biochemically verified abstinence at 6 months (Ferron, Devitt, McHugo, A Jonikas, Cook, & Brunette, 2016). There have been efforts to provide interventions across the spectrum of motivation that included interventions for those not motivated to quit. Williams et al., (Williams, Ziedonis, Vreeland, Speelman-Edwards, Zechner, & Williams, 2009) described a 20-session group wellness treatment designed to provide treatment for smokers with serious mental illness who may not be contemplating quitting smoking. Her description did not include any patient outcomes bearing on the efficacy of this treatment. Prochaska et al. (Prochaska, Hall, Delucchi, & Hall, 2014) recruited smokers from a locked acute psychiatry unit. Study participants were largely unmotivated; only 16% intended to quit smoking in the next 30 days. The researchers tailored the intervention to stage of change. It included a computer-delivered intervention, print materials, a cessation counseling session, access to NRT, and booster intervention contacts at 3 and 6 months post hospitalization. Compared to smokers randomly assigned to a usual care condition, verified abstinence was greater for those receiving the intervention at 18 months follow-up (20.0% vs. 7.7%). While promising, none of these studies provided an exclusively motivational intervention designed for smokers not motivated to quit delivered across multiple sessions in an outpatient treatment setting. We hypothesize that, compared to smokers randomly

assigned to an attention control group, smokers who receive an intervention that incorporates treatment elements known to motivate smokers in the general population will: exhibit increased motivation; greater engagement in cessation treatment; and greater likelihood of quitting.

Method

Participants

Clients from 12 Community Support Programs (CSPs) in Wisconsin served as study participants. CSPs are state-funded, county-managed intense outpatient treatment programs for those with severe, persistent and disabling mental illness. In order to receive care from a CSP, individuals must have: a) psychosis diagnosis; b) a significant risk of either continuing a pattern of institutionalization or living in a severely dysfunctional way without such services; and, 3) impairment of at least one area of vocational/educational/homemaker functioning, social, interpersonal/community functioning, or self-care/independent living (Wisconsin State Legislature, 2008). Typical diagnoses are schizophrenia, schizoaffective disorder, bipolar disorder and depression with psychotic features. Most CSP clients have multiple diagnoses. CSP clients either travel to the CSP for care or receive home visits. CSPs provide comprehensive services including counseling, medication management, housing/employment/transportation assistance, and socialization opportunities. Typically, CSPs treat patients for extended periods, often exceeding a year.

Recruitment occurred via flyers, designed to attract as many smokers as possible, posted at the CSPs. Flyers provided the study description, the enrollment contact person, and indicated the study was open to all smokers who were concerned about their smoking or were willing to talk about it. Flyers noted that participants were not required to quit, could potentially receive free nicotine patches and coaching, and payment for time spent. Interested smokers contacted study staff on their own. CSP staff did not announce the study. Interested smokers occasionally sought out CSP staff with questions. Their responses included referring the interested smoker to study staff. Interested smokers who contacted study staff learned the study had two options, one for those wanting to quit in the next 30 days (motivated) and one for those not wanting to quit in the next 30 days but willing to learn how to eventually quit or just cut down (unmotivated). Smokers then selected the most appropriate option for them. This was done to safeguard against smokers who were motivated to quit but portrayed themselves as not motivated just to gain entry into the study. Following patient selection of one of the options, study staff randomly assigned those not interested in quitting in the next 30 days to either the intervention group or attention control group. Those interested in quitting formed a comparison group. Inclusion criteria for the motivated-to-quit comparison group included 18 years of age or older, smoking daily or at least 10 cigarettes/week and plans to remain in the area for the next five months. Exclusion criteria were having a court-ordered guardian or an activated power of attorney or observations by researchers during the consent procedures suggestive of diminished decision-making capacity. Additional exclusion criteria for unmotivated smokers were: current use of any cessation medicine; previous serious skin reaction or other allergic reaction to using the nicotine patch; stroke, heart attack, or abnormal electrocardiogram in

the past four weeks; and, pregnancy, plans to get pregnant, or nursing. The University of Wisconsin IRB approved all study procedures, including obtaining written informed consent from members of a vulnerable population.

Interventionists

Four certified peer specialists and two research assistants provided the interventions. Peers were state-certified individuals in recovery from mental illness who complete state training and testing so they can support the recovery of others with mental illness by sharing their lived experiences. Consistent with the ability to share lived experience that is at the core of being a certified peer specialist, all the peer researchers were ex-smokers. Peers were selected to provide the interventions because of their ability to relate to those with significant mental illness and understand the barriers and challenges they face. Using peers increased the generalizability of study results because they were obtained by paraprofessional staff readily available in CSPs. Two research assistants augmented the peer researchers due to turnover and when a 12th CSP site was added. Peers underwent approximately 40 hours of training addressing the fundamentals of tobacco addiction, procedures for obtaining written informed consent and establishing eligibility, the administration of surveys to collect data, and how to provide the interventions. They conducted critiqued practice of all intervention elements and completed research with human participants and privacy training. A conference call with all the peer researchers and study staff occurred weekly during data collection to monitor study progress and compliance with adverse events reporting requirements, and to ensure fidelity to treatment protocols. In addition, research staff visited each CSP 1 – 2 times per month for observation and feedback. These visits included audio recordings of each intervention type. Research staff reviewed the recordings and provided corrective feedback as appropriate.

Procedures

This study took place either at the CSP in a private location or, occasionally, at a different community location that afforded privacy when requested by the participant and approved by the CSP. The same peer researcher/research assistant saw the enrolled participants for all visits except when there was peer researcher turnover. Following smoker self-identification as motivated to quit or not, obtaining informed consent, and establishing eligibility, all participants took a baseline survey. This survey consisted of 37 items (12 background/demographic questions including mental illness diagnoses, and current physical health, mental health, and stress level; ten questions about historical and current smoking and quitting history, including time to first AM cigarette as a measure of dependency; and 15 questions about current motivation to quit including questions to assess stage of change (DiClemente et al., 1991), and the short form of the Decisional Balance Inventory (Velicer, DiClemente, Prochaska, & Brandenburg, 1985; Ward, Velicer, Rossi, Fava, & Prochaska, 2004)). The peers offered to read the survey aloud, an offer that was frequently accepted. Participants received a \$10.00 gift card for completing this initial visit.

Participants not motivated to quit—Peer researchers assigned participants to either the intervention condition or the attention control condition based on a previously established

randomization table. Each participant then attended four weekly individual 20 – 30 minute intervention sessions receiving an \$8.00 gift card for each session attended.

Intervention: Each of the four intervention sessions consisted of engaging the participant in a motivational activity followed by a behavioral activity designed to prepare for a quit attempt. (see Figure 1) Session 1 involved reviewing past quit attempts, focusing on initial success and lessons learned as an opportunity to build self-confidence and self-efficacy and setting daily smoking goals to achieve about a 50% reduction in smoking. After reviewing the previous week, session 2 consisted of completing the decisional balance worksheet (Apodaca & Longabaugh, 2009) and planning for a 24-hour practice quit attempt. Peer researchers described this practiced quit attempt as short-term practice to prepare for some future quit attempt rather than an actual quit attempt. Completing the decisional balance worksheet included asking the participant to identify the important reasons to quit or not, which typically favor quitting, thus providing an opportunity to focus on “change talk” (Miller & Rose, 2015). Session 3 included an activity where participants imagined themselves as smoke-free at future time-points and then combined the behavioral assignments for the previous two sessions – setting a smoking reduction goal of 50% over six days with a practice quit attempt on the seventh. The fourth session was a review of the previous three. Additionally, the CSP pharmacy provided each participant with a supply of nicotine patches (21 mg/day) starting at the first intervention session and continuing through the fourth session. Peers monitored patch use for side effects.

Attention control: These four sessions lasted 20 – 30 minutes, thus providing the same exposure to the peer researchers but not the intervention content. Rather, participant and peer researchers reviewed booklets about the effects of smoking on body systems and the dangers of secondhand smoke that were developed for this study. Attention control participants also received the nicotine patch.

At the end of session 4, peer researchers explained the features of the Wisconsin Telephone Quit Line to all participants. Next, they invited each participant to make a call to the WTQL to initiate an evidence-based quit attempt (essentially, a warm hand-off). For those who agreed, the peer researcher called the WTQL. Next, the peer researchers told all participants that they could have four more optional weekly sessions, although such visits would not include any payment. Following this, each participant took a post-intervention survey. This survey consisted of 17 items focusing on smoking over the past 30 days and motivation/intent to quit including re-measuring the stage of change and the short form Decisional Balance Inventory (Velicer et al., 1985; Ward et al., 2004). As before, participants could have the survey read to them. Finally, the peer researchers confirmed participant contact information and reminded them of the three-month follow-up visit and its associated \$15.00 gift card.

The additional support provided to participants in the intervention condition who opted for four additional sessions drew on the motivational and behavioral activities begun in the first four sessions. The additional support provided to participants in the attention-control group who opted for four additional sessions drew upon the information about the effects of smoking on health presented earlier. Training provide to the peer researchers emphasized the

importance of not conducting any of the intervention activities during these optional sessions for participants assigned to the attention control condition. These optional sessions did not include the use of the patch.

Participants motivated to quit—The session for these participants included the study elements provided at the end of the fourth sessions for unmotivated participants: a description of the WTQL; an invitation to make a joint call; and an offer to meet four times. This did not include dispensing any patches. Those who opted to receive four additional counseling session received general support for quitting. These participants did not take the end of intervention survey as they had only one visit.

Three-month follow-up—The peer researchers contacted participants for a follow-up three months after the fourth visit for all participants not motivated to quit, and three months following the single visit with participants motivated to quit. Three-month follow-up was selected to reduce attrition and because previous research has documented that most intervention-related quit attempts and subsequent relapses occur within the first three months following treatment (Cummings, Jaen, & Giovino, 1985; Garvey, Bliss, Hitchcock, Heinold, & Rosner, 1992; Hughes, Keely, & Naud, 2004). The peer researchers collected smoking status at this visit and conducted biochemical verification (CO 6 ppm) with those who reported abstinence. Next, all participants took a follow-up survey. Questions varied by smoking status (7-day point prevalence). The survey for those who claimed abstinence consisted of 11 items about method of quitting, reasons for quitting and use of the WTQL. Those still smoking received a 23-item survey about amount of smoking, quit attempts in the past three months, motivation/intent to quit (including stage of change and short form of the Decisional Balance Inventory), and use of the WTQL. As before, participants could elect to have the survey read to them. Finally, peer researchers gave all participants a \$15.00 gift card and thanked them.

Outcomes

There were three core, main outcomes. First, accepting four more counseling sessions without reimbursement measures an increase in motivation to quit. Second, making a joint call to the WTQL to initiate an evidence-based quit attempt reflects both the decision to try to quit and behavior that successfully connects the participant with evidence based cessation treatment (Borland & Segan, 2006; Fiore et al., 2008; Lichtenstein, Zhu, & Tedeschi, 2010; Miller & Sedivy, 2009; North American Quitline Consortium, 2009). As a motivational study, measuring action taken (calling the WTQL and/or agreeing to four more sessions) is an appropriate outcome measure in that it may index intervention effects more sensitively than downstream outcomes (Baker, Mermelstein, Collins, Piper, Jorenby, et al., 2011). Increased motivation and engagement in evidence-based cessation treatment should result in increased abstinence. Biochemically verified 7-day point prevalence three months after the intervention is the third core outcome. We hypothesize an increase in joint calls to the WTQL, more acceptance of four more treatment sessions, and higher three-month abstinence compared to the control condition.

Data analysis examined two other types of data: demographic, health, and smoking history information for the purposes of assessing group equivalence at the time of randomization; and variables such as self-report changes in motivation/intent to quit (including stage of change and the short form of the Decisional Balance Inventory), smoking reduction, number of quit attempts, and number of days without smoking as secondary outcomes supportive of the main, core outcomes.

Analytic Plan

Data analysis included both a completer and a single imputation for missing values (missing data was assumed to be negative (choice not to call the WTQL, elected not to have four optional sessions, smoking [intent to treat]). Regarding the completer analysis, for the core outcomes measured at the end of the intervention (joint call to the WTQL and accepting 4 more sessions), Ns (%) for the intervention group and attention control group were 109 (93.4%) and 90 (86.5%, respectively. For abstinence, the Ns were 88 (80.7%), 58 (64.4%), respectively, and 25 (52.1%) for the comparison group. For intent to treat analyses, the Ns were 118, 104, and 48, respectively (see Figure 2: Consort Diagram). Dichotomous categorical data was tested by Fisher exact test; other categorical data, by Chi Square; and rating scales by t-test. Bonferroni correction addressed conducting multiple tests across the secondary outcomes. Data analysis used SPSS (IBM Corporation, 2013). There were separate data analyses for the comparison group. For the background/demographic variables, this analysis compared the comparison group (motivated) with the combined intervention group and attention control group (unmotivated). For the core outcomes, the analysis examined the comparison group with each of the unmotivated groups separately. Finally, data analysis contrasted the comparison group with intervention participants on the secondary, supportive outcomes to assess how similar the intervention participants became to the motivated comparison participants.

Results

Participant Recruitment and Retention

Three hundred and one CSP patients expressed an interest in the study; 54 (17.9%) indicated that they wanted to make a quit attempt in the next 30 days and 247 (82.1%) indicated that they did not want to quit. (see Figure 2). Of these 247 unmotivated smokers, 13 did not consent and 12 were not eligible. Of the remaining 222, 118 comprised the intervention group and 104 to the control group. Of the 118 intervention participants, 109 (92.4%) attended the fourth session and took the end of treatment survey; 90 (86.5%) of the control participants did so, ($p=.26$). These formed the groups for the completer analysis of the first two core outcomes, accepting additional counseling and calling the WTQL. More of the intervention participants received the three-month follow-up (88 or 74.6%) compared to 58 (55.8%) of the control participants (Fisher exact test, $p<.01$). These formed the groups for the completer analysis of the third core outcome, abstinence. The rate of follow-up for intervention participants (74.6%) was also significantly higher than from the follow-up rate for the motivated participants, 52.1% ($n=25$) (Fisher exact test, $p<.01$).

Almost all visits took place at the participating CSP. Three percent took place in a library. None took place in participants' homes. Peer researchers conducted 69% of the participant contacts; research assistants, 31%. Over 85% of the scheduled sessions took place. Over 90% of participants provided the nicotine patch used it on at least one day. While the researchers did not record patch compliance, those that did use the patch used it almost every day.

Group Equivalence

Random assignment should produce equivalence between the intervention and attention control groups. This was the case; there were no statistically significant differences between participants randomly assigned to the intervention and control groups on any of the 34 demographic, health, or historical/current smoking variables (see Table 1). The mean age in the total sample was 44, 48.3% were female, 86.7% had an annual income of less than \$25,000, and 73.3% were enrolled in Medicaid. 51.2% self-reported a diagnosis of schizophrenia; 54.6%, bipolar disorder; 45.4% a major affective disorder; and 14.2% alcoholism. (Participants could report more than one diagnosis.) The average self-rating of current stress was 7.8 on a 1 (none) to 10 (maximum) scale. The average age of daily smoking onset was 17; average daily cigarette consumption was about a pack per day - 21.5; 58.3% had their first cigarette of the day within 5 minutes of waking; and the average number of previous quit attempts was 8.7.

Because participants self-selected into the motivated or the unmotivated arm of the study based on their self-assessed motivation, participants in the comparison group should be more motivated. Compared with participants who did not want to quit in the next 30 days (intervention and attention control participants combined), those that wanted to quit in the next 30 days (comparison group) reported that: quitting was more important; they were more ready to quit; they had greater confidence about quitting; they were more willing to set a quit date in the next 30 days; and were more likely to be in the preparation stage of change (see Table 1). Also the comparison group was better educated (40.0% greater than a high school degree vs. 25.1%, respectively) ($p = .049$), less likely to self-report a major affective disorder (21.6% vs. 49.8%, respectively) ($p = .002$), and had lower self-reported current stress (6.7 on a 1 [none] to 10 [maximum] scale vs. 8.1, respectively) ($p = .037$). Interestingly, compared to the unmotivated participants, the comparison group of motivated participants perceived quitting as more difficult (8.0 on a 1 [very easy] to 10 [very hard] scale vs. 4.9, respectively) ($p < .001$) and more of them reported that all, or almost all, their friends smoked (51.3% vs. 31.8%, respectively) ($p < .001$).

Core Outcomes

Accepting four optional treatment sessions—60 intervention participants and 22 attention control participants agreed to receive four additional counseling session. This is a significant difference in both the completer analysis and in the intent to treat analysis (Fisher exact test, $p > .01$ for both). See Figure 3.

Calling the WTQL—Eleven intervention participants and 6 attention control participants agreed to and made a joint call to the WTQL. These call rates were not significantly

different ($p=.45$) for both completer and intent to treat analyses, Fisher exact test). Participants could have contacted the WTQL on their own between the last session and the three-month follow-up. Doing so was recorded on the three-month follow-up survey. Eight additional intervention participants and two additional control participants did so. Adding these to those who called at the last session results in a 16.1% call rate for intervention participants and 7.7% for control participants (intent to treat), a difference that approached but did not reach statistical significance ($p=.06$, Fisher exact test). The completer analysis was also non-significant.

Biochemically verified abstinence—At the three-month follow-up, 10 intervention participants and 1 attention control participant demonstrated biochemically confirmed abstinence. In the completer analysis, this difference is statistically significant ($p=.05$, Fisher exact test). In the intent to treat analysis this difference is also statistically significant ($p=.01$, Fisher exact test). It is difficult to measure outcome when there is study dropout, especially when there is more dropout in the control group. For this outcome, there was significantly more control dropout than intervention (44.2% vs. 25.4%, respectively; Fisher exact test, $p<.01$). To address this, we conducted a sensitivity analysis. Unlike the intent to treat analysis, in which we assume all those lost to follow-up are smokers, we assumed some of those lost to follow-up quit. Table 2 presents the abstinence results obtained under assumptions of increasingly greater quitting in the attention control group dropouts relative to the attention control group completers and increasingly less quitting among the intervention dropouts than among the intervention completers. All such analyses found the rate of quitting among the intervention participants was significantly greater than among the attention control participants.

Secondary, Supportive Outcomes

Self-report measures taken at the end of treatment and at the three-month follow-up were generally supportive of the core outcome measures (see Table 3). For example, at the end of treatment, intervention participants, compared to control participants, reported: smoking fewer cigarettes per day (12.6 vs. 18.6, respectively, $p<.001$); greater readiness to quit (5.4 vs. 4.0, respectively on a 10 point scale, $p=.001$); greater confidence about quitting (5.6 vs. 4.5, respectively on a 10 point scale, $p=.017$); greater willingness to set a quit date in the next 30 days (34.3% vs. 13.8%), $p=.002$; and, a stage of change more indicative of change (Precontemplative -30.4% vs. 31.3%, Contemplative -39.2% vs. 55.0%, Preparation -30.4% vs. 13.8%, $p=.029$). Similar differences were present at the three-month follow-up. In addition, among those still smoking at the time of follow-up, compared to control participants, intervention participants were more than twice as likely to report at least one quit attempt over the previous three months (50.0% vs. 21.4%, respectively, $p<.01$) and to have at least one day with no smoking (28.8% vs. 12.0%, respectively, $p<.05$). Only differences in daily smoking and readiness to quit at the end of treatment remained statistically significant after Bonferroni correction for multiple statistical tests.

Intervention Participants vs. Motivated Comparison Participants

Data analysis compared the intervention participants and those already motivated to quit (comparison participants) to determine how similar the intervention participants became to

the motivated comparison participants. Among the comparison participants, 14 opted for four additional counseling sessions. In the intent to treat analysis, comparison participants were significantly *less* likely to opt for the additional sessions ($p < .05$, Fishers exact test) (See Figure 3). Among the motivated comparison participants, 6 called the WTQL at their initial visit and 3 were abstinent at the 3-month follow-up. There were no differences between these two groups in the number who made a joint call to the WTQL (12.5% comparison, 9.3% intervention) or three-month biochemically verified abstinence (6.2% comparison, 8.5% intervention).

Discussion

A brief motivational and preparatory intervention delivered primarily by peer researchers to smokers with severe mental illness, who were not interested in quitting in the next 30 days, resulted in higher rates of treatment engagement, operationalized as willingness to continue treatment, (50.8% vs. 21.2%) and higher quit rates (8.5% vs. 1.0%) when compared to unmotivated smokers in the control condition. The cessation rate among unmotivated smokers randomized to the intervention condition was also very similar to the cessation rate of smokers already motivated to quit (6.2%). The secondary outcomes were supportive of these two main outcomes. At the end of treatment, those in the intervention group, compared to those in the attention control group, smoked fewer cigarettes, rated themselves as more ready to quit, and were more likely to set a quit date in the next 30 days. At the 3-month follow-up, smokers in the intervention group, compared to those in the attention control group, were more likely to have made a quit attempt, were more likely to have at least one smoke-free day, and had greater quit confidence. Contrary to our hypothesis, intervention participants were not more likely to accept a joint call to the WTQL than were control participants, although the observed difference was in the predicted direction. Anecdotally, CSP case managers report that many of their clients have had difficult interactions with others as a ramification of their mental illness. As a result, they are slow to trust unfamiliar people. This might increase the likelihood that smokers with a significant mental illness find it difficult to accept as tobacco intervention delivered by a stranger, over the phone. It might be best to deliver such interventions face to face. At the very least, additional support from a trusted source might be needed in order to make better use of a telephone quit line.

A large majority of smokers recruited for this study (82%) opted for the study arm for those who wanted to learn how to quit some day or to reduce smoking rather than the study arm for those motivated to quit in the next 30 days. In a study recruiting from the general population of smokers seeking care in primary care, only 30 percent opted for a study arm for reducing smoking; 70% joined the study are for those who wanted to quit in the next 30 days (Piper, Baker, Mermelstein, Collins, Fraser, et al., 2013). Furthermore, of the 18% who did express the motivation to quit in the next 30 days, about half were not yet in the preparation stage of change. (Smokers in the contemplative stage of change would not typically be described as motivated to quit. Yet some chose to join the study arm for smokers who want to quit in the next 30 days. This discrepancy warrants further study about how researchers measure and operationalize motivation to quit smoking.) Further, few of these 18% took a further step toward quitting such as calling the WTQL (12.5%) and accepting four more sessions (29.2%). Few actually quit (6.2%). Finally, unknown is the number of

smokers whose motivation to quit was so low they didn't even pursue joining the study. Taking these three perspectives about motivation to quit (the majority didn't join the quit portion of the study, those that did often didn't try to quit, and there were provably some unknown number of smokers who were so unmotivated that they didn't join the study) together underscores the need for effective motivational interventions for smokers who have significant mental illness.

The quit rate in this study was quite modest (8.5%). This is consistent with the quit rate reported by others across levels of treatment intensity, motivational level of smokers, and follow-up periods. For example, Dickerson et al., (Dickerson, et al., 2016) reported 10% sustained abstinence measured at the last intervention visit of smokers in the contemplation or preparation stage of change who received 24, one-hour group meetings and individual meetings. Similarly, Ferron et al (Ferron, et al., 2016) reported a biochemically verified quit rate of 9% six months after a single use of a motivational decision support system. Steinberg et al., (Steinberg, et al., 2016) reported somewhat higher biochemically verified abstinence in both their motivational interview group (16.3%) and the interactive educational group (10.2%). However, they measured abstinence at 1-month follow-up. Prochaska et al. (Prochaska, et al., 2014) actually reported an increasing quit rate over time: 13.9% at 3-month post psychiatric hospital discharge, 14.4% at 6 months, 19.4% at 12 months and 20.0% at 18 months. Their intervention included stage-tailored computer intervention, a stage-tailored print manual, an individual counselling session while hospitalized, intervention contacts at 3 and 6 months post discharge, and access to NRT. Interesting, while this study recruited from among all smokers admitted, the level of motivation among their study participants was very similar to the level of motivation of participants in this study of smokers not intending to quit in the next 30 days: 37.2% vs 31.3% in the precontemplative stage, 47.8% vs. 55.4% in the contemplative stage, and 15.0% vs. 13.3% in the preparation stage. Taken collectively, these studies underscore the need for interventions of significant intensity and duration that span the phases of quitting (Baker, et al., 2011) and reflect tobacco dependence as an unremitting chronic disease (Fiore, et al, 2008). Interventions will have to combine the three elements of evidence based tobacco interventions: counseling to increase skills, cessation medication, and interpersonal support (Fiore, et al., 2008).

This study adds to literature exploring the roles paraprofessionals can play in helping peers with mental illness quit smoking (McKay & Dickerson, 2012). These roles have included serving as group co-facilitators, individual counselors within a multi-faceted cessation program and as outreach specialists. For example, Williams (Williams, Dwyer, Verna, Zimmerman, Gandhi, et al., et al, 2011) describe a program employing Consumer Tobacco Advocates (peers) as counselors. Peers first held informational sessions at community agencies and then followed up by providing a 20-minute peer-to-peer intervention based on Steinberg's (Steinberg, et al., 2004) brief motivational intervention that also included CO level feedback. Dickerson et al., (Dickerson, et al., 2016) successfully used peers as co-facilitators of a group intervention. Peers also met one-on-one with group members. To these roles can now be added peers as researchers as they successfully administered the motivational interventions. This suggests good dissemination potential for this and other similar brief tobacco interventions for individuals with severe and persistent mental illness especially because a large portion of ex-smokers coping with serious mental illness indicates

an interest in helping peers quit (Dickerson et al., 2011) and find such work personally rewarding (Dickerson et al 2016).

There are a number of study limitations that underscore the need to replicate and expand this study. Several limitations derive from the two immediate outcomes: agreeing to and receiving four more sessions and calling the WTQL. This meant that some participants, distributed differentially across the groups, received more contacts. Also, the measurement of abstinence, which took place three months after the fourth scheduled session occurred less than three months after the final contact for those participants who had four optional sessions. Likewise, the three-month abstinence outcome might also reflect the impact of receiving services from the WTQL. However, there were no significant differences between the groups in rate of calling the WTQL. Thus, the difference in abstinence between the two groups might reflect the impact of the motivational intervention, the impact of additional sessions, the impact of the WTQL, or some interaction among these elements. Other limitations reflect the real world setting of the study and the use of peer researchers. Peer researchers were not blind to study condition. As they were not trained as researchers, it is possible that efforts to achieve fidelity were not entirely successful and elements of the motivational intervention were presented in the attention control condition. However, greater similarity in what peer researchers provided to participants in the two groups would have decreased differences in outcome rather than increased them. Finally, this study recruited from a single type of treatment program, Community Support Programs, which may have resulted in a sample of smokers with disabling mental illness that is not representative of all such individuals. For this reason, study results may not generalize to all such populations. Study strengths include the use of peers as researchers, its community location, the use of two ways to operationalize of an increase in motivation (accepting four more sessions and calling the WTQL) and biochemical verification of abstinence

People with a mental illness have a markedly elevated rate of smoking. This is especially true of those with a severe, persistent, or disabling mental illness. While most of these smokers desire to quit, the vast majority are unwilling to engage in a quit attempt using an evidence-based treatment. Finding effective ways to motivate them to make a quit attempt and use evidence-based treatments is important. This study demonstrated that a brief, four-session intervention that combines motivational and preparatory activities along with the use of an over-the-counter nicotine replacement medicine resulted in a greater willingness to engage in the quit process and a greater quit rate three months later.

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Glossary

Intent to Treat

a method of addressing missing data in which all missing data is assigned a value that reflects a failure to achieve the desired outcome.

Completer Analysis

analysis based on only those study participants who completed data collection up to a specified time point.

Sensitivity Testing

testing outcomes under a variety of assumptions about the nature of missing data to measure the robustness of an observed effect.

Community Support Program

intense outpatient treatment programs providing wrap round services (mental health care, physical health care, and social services) for individuals with disabling mental illness.

Certified Peer Specialists

People in recovery from mental illness that provide support for others by sharing their lived experience after receiving training and certification.

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Figure 1.
Session Content

¹ Wisconsin Tobacco Quit Line

Figure 2.
Consort Diagram

Figure 3.
Core Outcomes, Intent to Treat

Table 1

Group Equivalence

Variable	Intervention Group	Control Group	Motivated Comparison Group ¹
Demographics			
Age (<i>M</i>)	43.8 (9.9) ^a	43.6 (10.0)	45.0 (9.5)
Gender (% female)	49.0% (51)	46.7% (43)	50.0% (20)
Hispanic (% yes)	8.4% (8)	5.8% (5)	10.0% (4)
Race (% African American)	20.8% (21)	32.9% (27)	36.1% (13)
Education			
% less than HS/GED	24.2% (23)	23.9% (21)	30.0% (12)[*]
% HS/GED	50.5% (48)	51.1% (45)	30.0% (12)
% more than HS/GED	25.3% (24)	25.0% (22)	40.0% (16)
Health Insurance (% Medicaid)	76.3% (87)	72.9% (70)	65.9% (27)
Employment			
% out of work > 1 year	33.7% (34)	38.6% (34)	28.9% (11)
% out unable to work	29.7% (30)	34.1% (30)	31.6% (12)
Income (% <\$25,000)	82.5% (80)	88.2% (75)	94.6% (34)
Health			
Number of psychiatric diagnoses (6 max), (<i>M</i>)	2.15 (1.0)	2.33 (1.1)	2.16 (1.4)
% with Schizophrenia	51.4% (56)	46.8% (44)	62.2% (23)
% with Bipolar Disorder	51.4% (56)	60.6% (57)	48.6% (18)
% with Major Affective Disorder	50.5% (55)	48.9% (46)	21.6% (8)^{**}
% with Anxiety disorder	39.4% (43)	50.0% (47)	35.1% (13)
% with Alcoholism	12.8% (14)	11/7% (11)	24.3% (9) ³
% Other drug abuse disorder	9.2% (10)	8.5% (8)	18.9% (7) ⁴
Overall mental health (% poor/very poor)	23.7% (23)	26.8% (23)	18.0% (7)
Overall physical health (% poor/very poor)	34.0% (34)	41.0% (34)	25.0% (10)
Current stress rating, (1=none to 10=max), <i>M</i>	8.07 (2.0)	7.87 (2.0)	6.68 (2.6)[*]
Smoking			
Age of onset of daily smoking, <i>M</i>	17.0 (3.4)	17.0 (3.9)	16.7 (6.5)
Daily cigarettes, <i>M</i>	22.0 (10.5)	20.4 (9.6)	21.8 (19.6)
Smoking days in past 30, <i>M</i>	30.0 (5.7)	29.3 (3.5)	28.2 (5.9)
Time to 1st AM cigarette (% within 5 minutes)	62.9% (66)	58.6% (51)	46.3% (19)
How ready to quit, (1=not at all to 10=most), <i>M</i>	4.3 (2.4)	4.6 (2.6)	7.84 (2.5)^{**}
How important to quit (1=not at all to 3=extremely) (% extremely)	44.4% (44)	34.6% (27)	83.3% (30)^{**}
How hard to quit (1=very easy-10=very hard) <i>M</i>	4.9 (3.1)	4.9 (3.3)	8.0 (2.8)^{**}
Quit confidence (1=not likely-10=very likely) <i>M</i>	4.5 (2.9)	4.3 (2.8)	7.5 (2.4)^{**}
Past quit attempts (<i>M</i>)	7.8 (8.1)	9.1 (14.6)	9.8 (18.4)
Heard of WTQL ² (% yes)	42.7% (41)	39.2% (31)	60.0% (21) ⁵

Variable	Intervention Group	Control Group	Motivated Comparison Group ¹
If asked, will set quit date within 30 days (% yes)	18.6% (18)	22.9% (19)	76.9% (30)**
Would seek help to quit (% extremely likely)	41.0% (43)	35.3% (30)	48.8% (20)
Do friends smoke? (% all or almost all)	32.7% (34)	30.7% (27)	51.3% (20)**
Stage of change			
% precontemplative	31.3% (26)	34.2% (27)	5.4% (2)
% contemplative	55.4% (46)	54.4% (43)	45.9% (17)
% preparation	13.3% (11)	11.4% (9)	48.6% (18)**
Positive Decisional Scale (<i>M</i>)	11.6 (3.4)	11.6 (3.1)	10.9 (3.8)
Negative Decisional Scale (<i>M</i>)	10.9 (3.7)	9.8 (3.6)	10.4 (3.7)

* $P < .05$

** $P < .01$

¹ Statistical tests compare motivated group with combined intervention and control group (unmotivated)

² Wisconsin Tobacco Quit Line

³ $p = .07$

⁴ $p = .08$

⁵ $p = .06$

^a standard deviation when associated with a mean and n when associated with a percent

Note: dichotomous categorical data tested by Fisher exact test, other categorical data tested by Chi Square, rating scales tested by t-test

Table 2

Sensitivity Analysis for Three-Month Abstinence

	Assumption	Intervention Abstinence	Attention Control Abstinence	Significance
Completer Analysis	Abstinence of dropouts is ignored	11.4%	1.7%	p = .05
Intent to Treat	All dropouts assumed to be smoking	8.5%	1.0%	p = .01
Analysis 1	Quit rate is the same among dropouts as completers within the two groups (11.4% vs. 1.7%)	11.0%	1.7%	P < .01
Analysis 2	Quit rate for attention control dropouts (2.2%) is greater than the quit rate among attention control completers (1.7%) while the quit rate among intervention dropouts is less (10.0%) than the intervention completers (11.4%)	11.0%	1.9%	P = .02
Analysis 3	Quit rate for attention control dropouts (4.3%) is even greater than the quit rate among attention control completers (1.7%) while the quit rate among intervention dropouts is even less (6.7%) than the intervention completers (11.4%)	10.2%	2.9%	p < .04

Table 3

Secondary, Supportive Outcomes

Variable	End of Treatment		Follow-up ^I	
	Intervention Group	Control Group	Intervention Group	Control Group
At least one quit attempt in past 3 months (% yes)			50.0% (31)^a	21.4% (9) **
Number of quit attempts (<i>M</i>)			3.5 (2.8)	2.2 (2.4)
At least one smoke free day (% yes)			28.8% (19)	12.0% (6) *
Daily cigarettes (<i>M</i>)	12.6 (7.1)	18.6 (11.3) **⁶	13.5 (8.1)	15.4 (8.6)
Smoking days in past 30 (<i>M</i>)	26.9 (10.2)	28.8 (4.2) ³	26.4 (7.0)	28.1 (5.4)
Intend to quit in next two weeks (% yes)	24.2% (23)	11.9% (10) ²		
Definite to quit in next 30 days (1=not at all to 10=very) (<i>M</i>)	3.3 (2.9)	2.8 (3.0)	2.6 (2.5)	2.2 (2.4)
Definite to quit in next year (1=not at all to 10=very) (<i>M</i>)	6.0 (3.3)	4.8 (3.5) *	6.2 (3.1)	4.7 (3.2) *
Definite to quit in next 5 years (1=not at all to 10=very) (<i>M</i>)	7.5 (2.9)	6.8 (3.3)	8.0 (2.8)	6.7 (3.0) *
How ready to quit (1=not at all to 10=most) (<i>M</i>)	5.4 (2.8)	4.0 (2.8) **⁶	5.2 (2.5)	4.0 (2.8) *
How important to quit (1=not at all to 3 extremely) (% extremely)	53.7% (51)	37.5% (30) ³	48.4% (30)	31.1% (14) ³
How hard to quit (1=very easy to 10=very hard) (<i>M</i>)	7.7 (2.2)	8.4 (2.1) *	7.6 (2.1)	8.1 (2.2)
Quit confidence (1=not at all likely to 10=very likely) (<i>M</i>)	5.6 (2.5)	4.5 (3.0) *	5.7 (2.1)	4.5 (2.8) *
If asked, will set a quit date in next 30 days (% yes)	34.3% (34)	13.8% (11) **	17.5% (10)	13.2% (5)
Would you seek help to quit (1=not at all likely to 3=extremely likely) (% extremely likely)	49.5% (51)	34.1% (28)	50.0% (29)	39.5% (17)
Stage of change				
% precontemplative	30.4% (24)	31.3% (25) *	23.2% (13)	27.5% (11) ⁴
% contemplative	39.2% (31)	55.0% (44)	51.8% (29)	65.0% (26)
% preparation	30.4% (24)	13.8% (11)	25.0% (14)	7.5% (3)
Positive Decisional Scale (<i>M</i>)	12.2 (3.1)	11.5 (3.4)	12.5 (2.6)	12.1 (3.2)
Negative Decisional Scale (<i>M</i>)	11.7 (3.5)	10.7 (3.3) ³	12.5 (3.2)	11.2 (3.3) ⁵

*
 $p < .05$ **
 $p < .01$ ^I Of those still smoking at follow-up²
 $p = .052$ ³
 $p = .08$ ⁴
 $p = .09$ ⁵
 $p = .054$ ⁶ remains significant after Bonferroni correction^a standard deviation when associated with a mean and n when associated with a percent

Note: dichotomous categorical data tested by Fisher exact test, other categorical data tested by Chi Square, rating scales tested by t-test

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