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Publication Date

2020-04-01

DOI

10.1016/j.jsat.2019.12.012

Peer reviewed

Enhancing Engagement in Evidence-Based Tobacco Cessation Treatment for Smokers with
Mental Illness: A Pilot Randomized Trial

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Declarations of interest: none

Funding: This work was supported by grants from the Veterans Affairs Health Services Research & Development Service (HSR&D HX-001594-01) and the California Tobacco Related Disease Research Program (TRDRP 23XT-0004).

Keywords: smoking cessation; treatment utilization; brief intervention; motivational intervention; mental illness

1. Introduction

Declines in smoking rates over the past few decades have been much lower among individuals with psychiatric disorders than those without (Cook et al., 2014). Consequently, tobacco-related morbidity and mortality are disproportionately higher among individuals with mental illness, with tobacco-related diseases among the primary causes of premature death in this population (Colton & Manderscheid, 2006; Mauer, 2006). In addition, cigarette smoking may negatively affect psychological as well as physical health, serving to underscore the importance of addressing this behavior (Cavazos-Rehg et al., 2014; Krebs et al., 2018; Plurphanswat, Kaestner, & Rodu, 2017; Taylor et al., 2014). Smokers with psychiatric disorders typically have higher levels of nicotine dependence and poorer cessation outcomes and thus may particularly benefit from participation in structured treatment that includes both pharmacotherapy and behavioral counseling (combination treatment)(Smith, Mazure, & McKee, 2014; Ziedonis et al., 2008).

Military Veterans receiving health care at VA facilities have disproportionately high rates of psychiatric disorders as well as low incomes (Huang et al., 2017), identifying them as a tobacco related health disparity (TRHD) population at high priority for targeted smoking cessation interventions. Despite readily available access to tobacco cessation treatment within the VA system (Hamlett-Berry, 2004), few Veterans who smoke utilize formal tobacco treatment programming (Kelly, Sido, & Rosenheck, 2016). Of added concern, treatment utilization is low even among those accepting a smoking cessation clinic referral, these representing smokers with presumably higher motivation to quit. Among Veterans with psychiatric disorders referred to a smoking cessation clinic, only 23% of those who completed a brief telephone call to encourage treatment utilization attended a treatment session within 30 days of the contact (Petersen, Jubaiah, Chen, Doran, & Myers, 2018). As such, identifying strategies for increasing engagement in combination evidence-based treatment (ie.,combined pharmacotherapy and behavioral

counseling; (Fiore et al., 2008; Stead, Koilpillai, & Lancaster, 2015; Stead & Lancaster, 2012) for smokers considering cessation is of particular importance.

Several studies have investigated approaches to increasing smoking cessation treatment utilization, primarily with TRHD populations. These investigations typically incorporated principles of motivational interviewing (MI; Miller & Rollnick, 2012), based on findings that the beneficial effects of brief motivational interventions (MIs) are most pronounced when used proactively prior to formal treatment initiation rather than as a standalone-intervention (Lundahl, Kunz, Brownell, Tollefson, & Burke, 2010). Importantly, the efficacy of these brief interventions can be accounted for by enhanced engagement and utilization of evidence-based treatment rather than by increasing motivation for change alone (Burke, Arkowitz, & Menchola, 2003). For example, two recent studies employed proactive MI-based telephone calls to TRHD smokers as part of a protocol designed to enhance motivation for cessation, encourage treatment utilization, and facilitate treatment engagement and use of medications (Fu et al., 2014; Fu et al., 2016). In both studies, participants in the proactive care conditions reported significantly higher levels of treatment utilization and better cessation outcomes. Further, a number of studies have evaluated approaches to encourage treatment utilization and cessation efforts in smokers with serious mental illness (SMI). These have included studies of web-based interventions, demonstrating significant effects on treatment utilization and cessation outcomes (Brunette et al., 2013; Brunette, Ferron, Gottlieb, Devitt, & Rotondi, 2016; Brunette et al., 2011). Similarly, the utility of in-person brief motivational interventions has been demonstrated for enhancing treatment utilization and cessation outcomes in smokers with SMI (Steinberg, Williams, Stahl, Budsock, & Cooperman, 2016; Steinberg, Ziedonis, Krejci, & Brandon, 2004). Thus, prior evidence indicates that MIs hold promise for enhancing treatment engagement and utilization among TRHD smokers, including those with SMI. As demonstrated by our previous work (Petersen, Jubaiah, Chen, Doran, & Myers, 2018), treatment utilization is low even among Veteran smokers accepting referrals to

smoking cessation clinics. As such the present study focused on enhancing treatment utilization among smokers considering cessation.

We developed and evaluated the efficacy of a brief telephone-delivered MI-based intervention to facilitate engagement in evidence-based cessation treatment for military Veteran smokers with mental illness referred to a smoking cessation clinic. To our knowledge this was the first telephone-delivered brief intervention for engaging smokers with mental illness in formal treatment. It was also distinct from prior work by examining a component of an existing tobacco cessation treatment infrastructure, with a key goal being to facilitate engagement among smokers who have accepted a clinic referral. We report here on outcomes from a randomized pilot study comparing an MI-based treatment engagement intervention (TE) with a non-MI assessment and information control (CON) condition. The primary hypothesis of the study was that participants randomized to TE would have higher rates of utilization of evidence-based smoking cessation treatment (attending a treatment session, attending a session and using medication (i.e., combination treatment)) within 30 days of telephone contact than participants in the CON condition. Secondary hypotheses were that relative to the CON intervention, participants randomized to TE would have higher rates of self-reported 24-hour quit attempts and 7-day point abstinence from smoking 3 months following intervention.

2. Materials and Methods

2.1 Design. This parallel design trial included randomization to either TE or CON, stratified on the presence of SMI, (defined here as diagnosis of bipolar disorder, schizophrenia or another psychotic disorder). Assessments were conducted for all participants prior to allocation, 24 hours post-intervention, and at 1- and 3-months after intervention.

2.2. Participants. The study was reviewed and approved by the VA San Diego Institutional Review Board. To be eligible for this study, Veterans were required to meet the following criteria: ≥ 18 years of age, currently smoking any form of tobacco, and a referral to the outpatient tobacco cessation clinic for smokers with mental illness. Excluded were veterans unable to provide

informed consent, which was defined as patients with a conservator and/or who had active psychotic symptoms or severe cognitive limitations. Decisional capacity was assessed during a telephone screening with a trained research assistant (RA) by asking whether the respondent had a conservator and then again during the informed consent process by administering the University of California, San Diego, Brief Assessment of Capacity to Consent (Jeste et al., 2007). Informed consent was completed by telephone prior to the baseline interview. The IRB approved receipt of verbal consent for completing the baseline interview to facilitate timely study enrolment. Receipt by study staff of a signed consent form by mail or in-person was required prior to randomization/participation in the intervention. Psychiatric diagnoses were confirmed via a review of the participants' electronic medical record. All study-related visits, including eligibility screenings and assessment and intervention visits, were completed by telephone to minimize barriers to participation by reducing participant burden related to travel (time and expense), thereby facilitating enrollment of a more representative sample of participants and improving adherence to the assessment schedule. In addition, telephone interviews provided greater flexibility in scheduling interviews and participation for Veterans who lived at a distance from the research offices. The effectiveness of this approach is supported by achieving a 96% follow up rate. All 3 month follow-up assessments were completed by the end of November 2017.

CONSORT chart (Schulz, Altman, Moher, & Group, 2010) is presented in Figure 1.

Insert Figure 1 about here

2.3 Assessment. Following the eligibility screening, a baseline assessment was completed prior to the telephone intervention session. All participants completed a post-intervention assessment telephone call within 48 hours of receiving the telephone intervention that centered on evaluating treatment process variables and acceptability of treatment (working alliance). To evaluate treatment engagement following the intervention, attendance at VASDHS Tobacco Cessation

Clinics (in-person or by telephone) was monitored using Electronic Medical Records. Medical charts were reviewed, with participant permission, to confirm attendance in tobacco cessation clinics and prescription of smoking cessation medication (assessment of medication use relied on self-report). Finally, all participants completed follow-up assessments for key outcome variables (treatment attendance, attendance and use of medications, quit attempts, cessation). Given the potential difficulty of defining a quit attempt uniformly, we selected a definition that included both a stated intention to achieve long-term cessation and an ability to refrain from smoking as evidenced by a 24-hour period with no smoking (e.g. 'not even a puff').

2.4 Measures. All measures were administered at baseline and follow-up assessments unless otherwise noted.

Demographic information. Participant age, sex, marital status, race, ethnicity, employment, years of education, and income were assessed at baseline.

Smoking history. Years smoking, age at which smoking started, number and recency of past quit attempts, and prior use of the nicotine patch and other medications to quit smoking were assessed at baseline.

Recent Smoking. We used the Timeline Followback procedure (TLFB) (Brown et al., 1998; Robinson, Sobell, Sobell, & Leo, 2014) to evaluate participants' smoking in the prior 30 days or during the interval since the preceding interview, as appropriate. The TLFB interview is a calendar-assisted structured interview that provides a way to cue memory so that accurate recall is enhanced (Sobell, Brown, Leo, & Sobell, 1996). Self-reported attempts to stop smoking were recorded on the Timeline Follow Back (TLFB) calendar (i.e., first and last day of a quit attempt) at each follow-up assessment (Robinson et al., 2014).

Nicotine Dependence. The Heaviness of Smoking Index (HSI) (Heatherton, Kozlowski, Frecker, Rickert, & Robinson, 1989), a two item measure which has demonstrated validity for assessing nicotine dependence (Borland, Yong, O'Connor, Hyland, & Thompson, 2010), was utilized to

evaluate participants' nicotine dependence at each assessment. The HSI is based on number of cigarettes per day and time to first cigarette of the day, with scores ranging from 0 to 6.

Intentions for change. We used the 4-item Stage of Change algorithm (Velicer, DiClemente, Prochaska, & Brandenburg, 1985) at each interview to classify subjects into precontemplation, contemplation, and preparation stages of change with regard to their smoking

Smoking cessation cognitions. To assess thoughts and beliefs about quitting participants were administered the Commitment to Quitting Smoking Scale (Kahler et al., 2007) and the Thoughts About Abstinence Scale (Hall, Havassy, & Wasserman, 1990). The Commitment to Quitting Smoking Scale (CQSS) is an 8-item questionnaire that incorporates items reflecting intentions to persist with cessation efforts in the face of difficulty and discomfort. Responses are summed with higher scores representing greater commitment to quitting. The Thoughts About Abstinence scale assesses desire to quit, expected success in quitting, and anticipated difficulty remaining abstinent, each scored on a 1 to 10 Likert type scale. Higher scores reflect stronger desire to quit, more anticipated success quitting, and greater difficulty abstaining.

Treatment adherence and acceptability. The Motivational Interviewing Treatment Integrity Code (MITI4)(Moyers, Manuel, & Ernst, 2014) was used to assess adherence. The MITI is a procedure for assessing fidelity to MI principles and is widely used to establish MI treatment fidelity. Acceptability of the intervention was evaluated at the post-intervention assessment using the Working Alliance Inventory – Client (Horvath & Greenberg, 1989). The WAI is a widely used measure of working alliance in psychotherapy research and has demonstrated validity and reliability (Horvath & Greenberg, 1989). For the present study we utilized 8 of the 12 items from the short-form Client version of the WAI, adapted for smoking cessation, and employed a 4-point Likert scale coded such that higher scores reflect a better working alliance.

2.5 Randomization. The study utilized a computerized urn randomization procedure, stratified by presence or absence of a medical chart SMI diagnosis (bipolar disorder, schizophrenia, other psychotic disorders), and outcome models included this index in the set of planned covariates.

The interventionists, who administered both conditions, performed randomization immediately prior to making the intervention phone call and were responsible for maintaining the list linking subject ID with condition assignment. Allocation was intended to be balanced across conditions, however a software error resulted in greater than planned allocation to the TE condition. Research assistants conducting assessments and the investigators were blind to treatment allocations.

2.6 Intervention. Content and format of the TE condition were developed employing a qualitative treatment development process utilizing an iterative design whereby information from successive phases was used to refine intervention content and delivery (Hsieh & Shannon, 2005). Information from qualitative interviews with 16 Veteran smokers was utilized to produce a pilot protocol and manual. The intervention protocol was iteratively modified during this process with a final draft produced incorporating feedback received from participants, input from an MI consultant and study interventionist. In the final phase we conducted four pilot intervention telephone calls during which each participant was administered the TE intervention and subsequently interviewed regarding their experience of the intervention process and content. The final intervention protocol incorporated feedback from the participants' qualitative interviews and input from study investigators and the MI consultant.

The TE intervention was designed specifically to facilitate engagement in existing treatment programs. The key MI techniques incorporated included open-ended questions, reflections, affirmations, summaries and forming a plan (if appropriate). The first section of the protocol centered on assessment of current tobacco use, past quit attempts, current intentions to change, and importance and confidence in quitting. The assessment portion concluded with the interventionist summarizing the prior discussion and (if appropriate) asking permission to provide information regarding available resources. Participants were provided with a description of the purpose of smoking cessation medications and behavioral counseling, information regarding treatment effectiveness, and a description of the available local resources for smoking cessation.

After providing information, the interventionist invited questions and asked the participant what they would like to pursue as the next step. Participants who indicated a desire to participate in smoking cessation treatment were provided with information regarding participation (times, days, location for groups; referral to telephone clinic), proactive referrals were placed as appropriate (e.g., request for proactive contact by telephone clinic), and efforts were made to facilitate medication orders for those interested in receiving smoking cessation pharmacotherapy. The TE sessions were approximately 20 minutes in duration.

The comparison condition (CON) included the same assessment questions and informational content regarding treatment efficacy and available resources, as well as providing referrals and facilitating procurement of medication as appropriate. However, it was administered in a didactic fashion, without employing MI techniques (e.g., using only closed ended questions, no reflections or summaries). Each CON session lasted approximately 10 minutes. Table 1 outlines differences across the treatment conditions. Interventionists participated in bi-weekly supervision with an MI consultant involving review of audio recordings to ensure treatment fidelity. In addition, treatment fidelity was formally assessed by submitting 10 randomly selected session recordings from each condition to be scored using the Motivational Interviewing Treatment Integrity Code (MITI4)(Moyers et al., 2014) by an MI coding consultant unaffiliated with the study. MITI global scores indicated that TE sessions reflected good MI practice while the control intervention scored poorly. The global score component of the MITI coding employs summary scores ranging from a minimum of 1 to a maximum of 5. Global scores were computed for Technical (cultivating change talk, softening sustain talk) and Relational (partnership and empathy) dimensions of the sessions. In support of treatment adherence for the TE and CON conditions, the average Global Technical Scores were 4.5 (sd=.58) and 2.5 (sd=.88) respectively. Similarly, the TE condition sessions averaged a Global Relational score of 4.4 (sd=.94) while the CON sessions scored on average 2.05 (sd=.90). Successful implementation and perceived acceptability of the TE condition was further supported by participant rated working alliance, with

scores for the TE participants indicating significantly higher alliance than for CON participants (30.5 (2.1) vs 28.7 (3.4), $p = .004$).

Insert Table 1 about here

2.7 Outcomes. The primary treatment engagement outcome was defined as a) having completed at least one treatment session within 30 days of the intervention phone contact¹, and b) having attended a treatment session and used smoking cessation medications within 30 days of contact (combination treatment). Additional outcomes evaluated post intervention included attempts to quit smoking, defined by a self-report of at least one quit attempt with at least 24 hours of no cigarette/tobacco smoking; and 7-day point-prevalence abstinence from cigarettes (PPA), defined as a self-report of no cigarettes/tobacco smoked in the last 7 days.

2.8 Sample Size. Empirical power analysis was conducted to select a sample sufficient to detect moderate to large effects on treatment engagement and sustain power >0.80 for tests of statistical significance ($\alpha <0.05$). With observed rates of engagement in our veteran population of 7% and previously observed rates of treatment engagement (defined as scheduling a tobacco cessation treatment appointment) of 32% among smokers with serious mental illness receiving a motivational intervention (Steinberg et al, 2016) suggesting potential odds ratio of 3.34 (32% vs 7%) we chose our targeted sample size of 80 to maintain desired power. The imbalance in assignment across groups may have decreased precision in estimating the proportion engaging treatment in the CON arm relative to precision of estimates in TE. However, given the expected effect size was larger than that observed (47% vs 45%) and the small imbalance in allocations there was no

¹ The telephone clinic averaged 3-4 weeks until first available appointment during the study period, thus for some participants the first session was not available until after the 30 day follow-up period. To account for this, all participants whose initial telephone clinic appointment was confirmed within 30 days and subsequently completed (even if outside the 30 day window) were coded as having met the 30 day engagement criterion.

significant decrease in power for the primary hypothesis. This pilot was not powered to detect expected clinically significant differences in abstinence from cigarettes/tobacco.

2.9 Statistical Methods. All outcome analyses included an intention to treat sample as shown in Figure 1. The primary outcome of treatment engagement at 1-month and self-reported 24-hour quit attempts and PPA at 3-months were analyzed employing logistic regression with planned covariates for gender, income (above or below 2018 Federal poverty level) (USDHHS, 2018), presence of SMI, and levels of cigarette dependence given strength of relationships with cessation outcomes in prior studies (McKee, Smith, Kaufman, Mazure, & Weinberger, 2016; Rae, Pettey, Aubry, & Stol, 2015; Reid, Hammond, Boudreau, Fong, & Siahpush, 2010; Velicer, Redding, Sun, & Prochaska, 2007). Stage of change (dichotomized as precontemplation/contemplation versus preparation) was included as an additional control variable based on baseline differences across groups. All models estimated between-group differences and subsequently the interaction to assess whether differences between smokers with and without SMI differed across conditions (Group X SMI). Ordinary least squares regression models were used to evaluate between group differences in quitting related cognitions.

3. Results

3.1 Sample Characteristics. Table 2 reports demographic, mental health, and smoking characteristics of the participants allocated. Smokers were predominantly male and represented a broad range of age groups and racial/ethnic backgrounds. Multiple psychiatric diagnoses were common (68%), and 44% had a substance use disorder history. Approximately 21% and 26% had a severe mental illness diagnosis (Bipolar, Schizophrenia, Psychotic Disorder) in TE and CON, respectively.

Insert Table 2 about here

3.2 Treatment Engagement. (See Table 3) Following intervention delivery 47% of TE and 45% of CON participants reported attending a treatment session during the subsequent 30 days. There was no significant difference in the likelihood of treatment engagement (AOR=0.98, 95%CI = 0.39-2.43), $p=0.96$), and none of the covariates predicted engagement. When classified as utilizing combination treatment, 40% of TE versus 18% of CON reported treatment including use of smoking cessation medication and behavioral counseling, a statistically significant difference (AOR = 3.23, 95%CI= 1.02 – 10.16, $p=0.04$). In addition to treatment condition, smokers below the poverty line were less likely to utilize combination treatment (AOR = 0.88, 95%CI= 0.07 – 0.88, $p=0.03$). Likelihood of any treatment engagement (AOR=1.21, 95%CI= 0.41 – 3.54, $p=0.73$) or utilizing combination treatment (AOR=2.04, 95%CI= 0.57 – 7.28, $p=0.27$) did not differ significantly for those with and without serious mental illness.

We examined utilization of treatment sessions and medication types for the entire followup period. No differences emerged on number of sessions attended nor on types of medications used. Among those who attended any treatment sessions, the average number for those in TE was 2.70 (2.01) versus 2.24 (1.30) sessions for CON participants. Overall, similar proportions within each condition reported using smoking cessation medications during the follow-up period (68.8% of TE, 63.2% of CON). For those in TE who reported use of smoking cessation medications, 84.4% used nicotine replacement, 12.5% bupropion and 3.1% varenicline. In comparison, among CON participants using medications, 70.8% used nicotine replacement, 20.8% bupropion and 8.3% varenicline.

3.3 Cessation outcomes. (See Table 4) During the three months following treatment no significant difference was observed between TE (60%) and CON (66%) participants on reports of at least one quit attempt of 24-hours or longer (AOR= 0.62, 95%CI=0.24 - 1.64, $p=0.34$). Although participants in the TE condition self-reported higher rates of 7-day PPA at the 3-month assessment than those in CON (30% vs. 18%, respectively), the difference was not statistically significant (AOR = 1.64, 95%CI = 0.51 – 5.28, $p = 0.41$). A trend was observed whereby smokers

with compared to those without serious mental illness reported lower odds of success in achieving 7-day PPA (11% vs 30% respectively) (AOR = 0.61, 95%CI = 0.11 – 3.44, $p = 0.06$).

Insert Table 3 about here

3.4 Treatment effects on quitting related cognitions. Exploratory analyses were conducted to examine whether changes in smoking cessation cognitions were related to treatment assignment. We separately examined between group differences on desire to quit, expected success quitting, perceived difficulty quitting, and commitment to quitting during the post-treatment interview (see Table 4). Regression models were adjusted for corresponding baseline values and planned covariates (gender, income, SMI, tobacco dependence). Participants in the TE condition did not differ from those in CON on post-treatment desire to quit ($b=-0.24$, $se=0.28$, $p=0.40$) or perceived difficulty in quitting ($b=-0.01$, $se=0.48$, $p=0.98$). However, smokers receiving TE had significantly higher beliefs for expected success in quitting ($b=0.99$, $se=0.47$, $p=0.04$) and higher commitment to quitting smoking following intervention than those in the CON condition ($b=2.85$, $se=1.20$, $p=0.02$).

Insert Table 4 about here

4. Discussion

The present study reports on outcomes of a randomized pilot investigation of an MI-based brief telephone intervention (TE) intended to enhance smoking cessation treatment engagement for Veteran smokers with mental illness. The primary outcomes examined were a) attending at least one counseling session and b) attending counseling as well as using smoking cessation medications (combination treatment) within 30 days of the telephone intervention. Although no differences were observed across conditions on session attendance, participants assigned to TE were significantly more likely to report engaging in combination treatment than

those in CON (40% versus 18%, respectively). No significant differences were observed across conditions on secondary outcomes consisting of making a 24-hour quit attempt and self-reported 7-day point abstinence at 3 months post intervention. Thus, initial findings support evidence for efficacy of the TE intervention in effecting increased utilization of smoking cessation counseling plus medication use.

The TE intervention developed for this study employed MI techniques and principles and the intervention consisted of an assessment of tobacco use, prior cessation efforts, and current intentions for change followed by providing information, with the participants' permission, regarding evidence-based treatment and available resources and programs. Participants interested in obtaining medications were assisted with this (e.g., by placing a request with referring provider) and referrals were placed for those interested with the local proactive telephone tobacco cessation clinic. The comparison condition included the same assessment and information content as well as medication facilitation and clinic referral, and differed by employing a didactic interaction that did not employ MI techniques. Thus, we chose an active rather than minimal control condition and also included several planned covariates in the analytic models, yielding a conservative evaluation of intervention efficacy. Both conditions yielded similar rates of treatment engagement, as indicated by attending a treatment session within 30 days of the telephone intervention contact. However, participation in the TE condition more than doubled (AOR=3.23) the likelihood of employing combination treatment consisting of both session attendance and use of medication. This finding provides support for the potential utility of this relatively brief and easy to deliver intervention for engaging smokers with mental illness in combination treatment. However, it is noteworthy that both conditions yielded high rates of treatment attendance, indicating their value for enhancing treatment utilization.

The pilot study was planned with sufficient statistical power to evaluate treatment engagement, but not cessation outcomes. However, an important goal of the intervention was to enhance cessation outcomes through treatment engagement. No statistically significant

differences between conditions were evident for cessation outcomes. However, there may be value to a larger scale evaluation that is adequately powered to assess cessation effects and incorporates biochemical validation of abstinence.

The small sample size precluded formal evaluation of potential treatment mechanisms and as such we did not examine mediation. However, we explored treatment fidelity and process variables, including working alliance and smoking cessation cognition variables. Ratings of randomly selected TE and CON sessions were conducted by an independent expert rater utilizing the MITI coding system (Moyers et al., 2014). These ratings clearly indicated that the TE sessions were consistent with MI principles whereas CON sessions were not. In addition, participant post-intervention rating of working alliance indicated that TE participants perceived having a significantly stronger alliance with the interventionist than did those in the CON condition. These results are congruent with the client-centered approach and emphasis on empathy in MI (Miller & Rollnick, 2012). Notably, a previous study of MI based brief telephone counseling for smoking cessation found that working alliance mediated the relationship of active counseling with quit attempts (Klemperer, Hughes, Callas, & Solomon, 2017), supporting the potential role of working alliance on the effects observed in the present study.

In a preliminary effort to address possible mechanisms of treatment we examined baseline and post intervention scores on desire to quit, anticipated difficulty quitting, expected success quitting and commitment to quitting smoking. After controlling for planned covariates, TE participants had significantly higher increases in expected success quitting and commitment to quitting than those in the CON condition. While preliminary, these findings are congruent with the MI goals of increasing self-efficacy for and commitment to behavior change. In particular, commitment to change has been found to predict smoking cessation (Amrhein, Miller, Yahne, Palmer, & Fulcher, 2003; Kahler et al., 2007). While speculative at this point, it may be that these effects of treatment influenced the observed differences in utilization of combination

treatment. Overall, these preliminary analyses support the fidelity and acceptability of the TE intervention and provide direction for future examinations of underlying treatment mechanisms.

The TE intervention examined here was developed and evaluated on smokers with mental illness. Of note, many study participants had multiple psychiatric diagnoses, and over 20% had a serious mental illness (SMI). Comparison of participants with and without SMI indicated no differences in rates of engagement across these groups. This finding is consistent with prior research demonstrating the effectiveness of motivational efforts to increase treatment utilization by SMI smokers (Brunette et al., 2016; Brunette et al., 2011; Steinberg et al., 2016). However, whether the TE intervention evaluated here is superior to the CON condition for smokers with SMI remains to be demonstrated. Consistent with commonly observed outcomes for smokers with SMI (de Leon & Diaz, 2005; Siru, Hulse, & Tait, 2009), participants with SMI in the present study were less likely than those without SMI to report a 24 hour quit attempt (55% vs 65%) and 7 day abstinence (11% vs 30%). Overall results of the study suggest that the TE intervention is acceptable to and effective for increasing combination treatment engagement for this important population.

A number of limitations indicate that the present findings be interpreted with caution. First, the small sample size provided limited statistical power to assess outcomes. In addition, the sample was predominantly male, as is often the case with studies of Veterans. As such, whether these findings generalize to women (and non-Veteran smokers with mental illness) remains to be demonstrated. Further, our definition of mental illness was based upon medical chart diagnoses which may be outdated or inaccurate. Although our intervention was intended to enhance motivation for utilizing treatment, we did not measure this directly and so cannot draw conclusions about the treatment mechanism by which TE led to increased treatment engagement. Also, the intervention was conducted with smokers who had accepted a referral to treatment, which may have influenced the observed session attendance rates. Finally, cessation outcomes relied on self-report, suggesting these be interpreted with caution as mixed support

exists for the veracity of self-reported smoking cessation (Scheuermann et al., 2017; SRNT, 2002; Velicer & Prochaska, 2004). While use of medications relied on self-report we were able to corroborate medication orders (i.e., whether participants were provided with medications) through medical chart review. Strengths of the study are that it was implemented within the context of an existing clinic, thus enhancing generalizability to VA settings. Furthermore, this telephone delivered intervention is relatively brief and accessible to smokers, thus reducing barriers to implementation.

5. Conclusions

The present pilot study provides initial evidence for the feasibility, acceptability and efficacy of a telephone delivered TE intervention for enhancing engagement in combination treatment in a sample of Veteran smokers with mental illness. These findings are especially important in the context of low rates of utilization of evidence based smoking cessation interventions among Veteran smokers (Kelly, Sido, & Rosenheck, 2016), including those accepting treatment referrals (Petersen et al., 2018) which contrasts with the ready availability of smoking cessation medications and counseling within the VA Healthcare System (Hamlett-Berry, 2004). These findings are also promising because of the population examined; smokers with mental illness are a population who typically have greater difficulty stopping smoking than those without mental illness (Lipari & Van Horn, 2013; Smith et al., 2014). Increased engagement in combination treatment thus has the potential to increase quit rates and ultimately reduce the burden of tobacco use for this population. Larger scale studies are needed to provide added support for the utility of this approach, in particular with respect to cessation outcomes, and to elucidate the underlying mechanisms of treatment.

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