Feasibility and early outcomes of a tailored quitline protocol for smokers with mental health conditions.

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Abstract

Introduction: Adults with mental health conditions (MHCs) smoke at higher rates, are more nicotine dependent, and have more trouble quitting smoking than those without MHCs. About half of smokers who call state-funded quitlines report MHCs, and those with such conditions have cessation rates 8-10% lower than those without MHCs. This paper describes a clinical pilot of a tailored protocol for quitline callers with MHCs. Methods: Callers to the Texas Tobacco Quit Line (TXQL) who self-reported MHCs were offered a tailored quitline program, offering up to 12 weeks of combination nicotine replacement (nicotine patch plus gum or lozenge) and seven counseling calls. Characteristics, program engagement, and 7-month outcomes for these pilot participants were compared to callers in the standard TXQL program with and without MHCs not offered the tailored program. Results: Eighty-eight percent of eligible quitline callers accepted enrollment in the tailored pilot. Pilot enrollees (n = 311) had high rates of co-morbidity and serious mental illness, including bipolar disorder (59%). Those in the pilot sample participated in more coaching calls and used more nicotine replacement versus comparison groups. Early cessation outcomes showed numerically higher quit rates for pilot participants than those with MHCs in the standard program, but small sample size and low response rates prevent definitive statements about efficacy. Conclusions: Offering a tailored quitline protocol for callers with MHCs was feasible and acceptable to quitline callers and increased engagement in treatment. A larger study is needed to determine if the protocol increases cessation among this group.
Implications

Nearly half of all quitline callers report a mental health condition. This clinical quality improvement pilot shows that delivering a tailored tobacco cessation program for smokers with mental health conditions is feasible and acceptable to quitline callers. Participants in the pilot group had higher engagement in treatment, doubling the number of coaching calls received and using more nicotine replacement than comparison groups. Further investigation is needed to determine the effect of this program on cessation rates, although preliminary outcomes are promising.
INTRODUCTION

Adults with mental health conditions (MHCs) smoke at higher rates than the general population.\(^1\) Smoking prevalence is particularly high among those with serious mental illness, with recent estimates ranging from 40 to 60% for schizophrenia and bipolar disorder as compared to 17% for those without a MHC.\(^2\) It is estimated that up to half of those diagnosed with schizophrenia, bipolar disorder, or major depressive disorder will die from tobacco-related illnesses.\(^3\) Those with MHCs are not only more likely to smoke, but they are heavier smokers, are more dependent on tobacco, and have more withdrawal symptoms than those without MHCs.\(^2,4,5\) Barriers to cessation treatment whether financial, systemic (e.g., lack of training for healthcare providers) or cognitive (e.g., beliefs that smoking reduces stress) can be particularly problematic for those with MHC.\(^6-8\) However, many smokers with MHCs want to quit smoking and do make cessation attempts.\(^9,10\) Evidence-based treatments are effective for those with MHC, including serious mental illness and substance use disorders.\(^11\) However, even with evidence-based treatment, cessation rates are lower among those with MHCs.\(^1,10,12,13\) Despite a recent increase in research publications regarding tobacco and MHCs, few studies have evaluated cessation interventions tailored for this disparate population,\(^4,14\) and many studies exclude those with serious MHCs.\(^15\)

Tobacco quitlines provide cessation services to more than 400,000 smokers in the US each year,\(^16\) and about half of callers to state-sponsored quitlines report at least one MHC.\(^12,13,17\) Recent evidence suggests that state quitline callers with a MHC have less success quitting, with cessation rates 8-10% lower than those without a MHC, despite equivalent engagement in treatment.\(^12,13,18,19\) Effective interventions to reduce tobacco use and its burden are sorely needed for this disproportionately affected group.\(^4\)
Quitlines are a strongly recommended as treatment strategy by the US Public Health Service (PHS) Guidelines and the National Cancer Institute (NCI) and can reduce barriers to cessation treatment. They are available in all 50 states and two US territories (Washington D.C. and Guam) and provide individual, confidential, free cessation counseling by trained staff in several languages, and most are open seven days a week. Quitlines provide at least a one-call counseling program (when the smoker calls the quitline) and most states provide additional proactive calls (where the quitline calls the smoker to continue treatment, typically for a total of four to five calls). Programs providing multiple proactive calls are more efficacious than single-call programs. Quitlines may also offer services via the internet, text messaging, and self-help materials, and some level of nicotine replacement therapy (NRT) is often offered. Quitlines’ anonymity, provision of scalable services on a population level, and easy access make them an ideal conduit for specialized tobacco services, but no trials of tailored quitline services for those with MHC have been published.

US PHS Guidelines recommend combining medication and behavioral counseling for the best cessation outcomes. Questions still remain, however, regarding how to tailor the standard quitline program to best meet the needs of smokers with MHCs. Furthermore, there are also questions about the feasibility of providing services tailored for this population in the context of the quitline where interventions are brief, standardized, and not delivered by mental health counselors.

Given that approximately half of the over 400,000 quitline callers each year report one or more MHC, tailored programs that can be delivered to a large volume of callers through the tobacco quitline model are needed to improve outcomes for callers with MHCs and to continue to decrease overall rates of smoking in the US. Optum, a large service provider of state
quitline services, developed and pilot tested a tailored quitline protocol for those self-reporting one of seven MHCs in partnership with the Texas Tobacco Quit Line (TXQL). This paper reports on the feasibility and preliminary outcomes of this Tobacco Cessation Behavioral Health Program (TCBHP).

METHOD

The pilot study began as a clinical quality improvement project in 2016. Permission to analyze the pilot data and data from comparison groups for research purposes was obtained in July 2017 from the Western Institutional Review Board.

Interventions

Standard Texas Tobacco Quit Line (TXQL) Services (Provided to Comparison Groups)

In the standard TXQL program, participants were offered five coaching calls, and callers who were uninsured, residents of specific counties, or fax-referred were eligible for one 2-week shipment of nicotine patch, gum, or lozenge; Medicaid-insured callers were not eligible for NRT. The PHS Guidelines-based Quit For Life® program is offered by Optum to state quitline participants, and its effectiveness has been well documented. The cessation program emphasizes five keys to quitting tobacco: setting a quit date, using medication, tobacco-proofing the environment, coping with urges and cravings, and garnering social support. The Quit For Life® program typically consists of 4 or 5 calls and is participant-focused with the timing of calls is determined by the participant’s quit plan and preferences. Typically quit dates are set 14 to 30 days following the first call (to allow for pre-quit planning and for medication to arrive). All TXQL callers (including pilot participants) could also enroll in an internet intervention (Web Coach®) and/or an automated text messaging program (Text2Quit®). Both Web Coach® and
Text2Quit® are interactive programs. Web Coach® offered an interactive quit plan development module and educational content based on Quit For Life® content in the coaching calls. Text2Quit® primarily involves being sent text messages tailored around a participant’s quit date, but also offers automated interactive texting where a participant can text a keyword to the program (e.g., “crave” when they have a craving) and receive one of several pre-programmed responses (e.g., advice to play a game for distraction).

**TCBHP: Tailored Intervention for Smokers with MHC**

In general, the TCBHP relied on the same evidence-based treatment model as the standard quitline and utilized strategies aimed at increasing the efficacy of standard quitline protocols (e.g., more interactions with the coach, more and longer duration of NRT). The TCBHP differed from typical quitline services with regard to coaching calls, medication provided, and addition of a letter to medical or mental health providers. The TCBHP was developed by clinicians at Optum with consultation from expert advisers and with reliance on treatment methods prescribed in the PHS Guidelines.21

For this pilot, the content of the standard Quit For Life® program was maintained with several changes. First, participants were offered seven calls instead of the standard five calls in order for participants to have more opportunities for tailored support. Number of coaching calls has been found to be related to cessation outcomes in quitline research with more calls leading to better quit rates.29 Standard TXQL and the pilot program participants were attempted three times for each call. Second, stress (a commonly cited reason for relapse) was added as a mandatory assessment question for every call in order to ensure this topic was addressed. Third, coaches were given additional clinical training in working with participants with MHCs that focused on
flexing communication style to match/complement that of the participant. The coaches were also offered additional support and supervision.

NRT has both been shown to be well tolerated and effective for those with MHCs.\textsuperscript{33,34} Combination NRT (using a longer-acting form of NRT such as the patch simultaneously with a shorter-acting form such as the gum or lozenge) has been found to be more effective than monotherapy\textsuperscript{35,36} and was chosen for use in this pilot. Similarly, longer duration of use has been shown to be more effective than shorter duration and 12 weeks of NRT was provided in the pilot.\textsuperscript{36,37} All pilot participants were screened for NRT use exclusions (e.g., recent heart attack, stroke, previous side effects), and those found eligible were offered 12 weeks of combination NRT (i.e., nicotine patch plus choice of gum or lozenge). Standard practice was followed for those participants who reported use exclusions, but wanted to use NRT: they could have a healthcare provider fax a letter to the quitline clearing them for NRT use. Participants were not required to use NRT: if they were unable to or chose not to use NRT, they were still able to participate in the pilot. Further, they could opt for monotherapy (e.g., patch only) rather than combination NRT. NRT was offered in three shipments of four weeks each, and each shipment was triggered by the participant engaging in a coaching call. The first shipment was sent after the first call. The second and third shipments were sent after subsequent calls and timed to prevent the participant running out of medication. Shipment timing was not standardized, however, as participants varied widely in the timing of their calls. NRT use exclusions were re-assessed prior to each shipment being sent.

Finally, the tailored protocol attempted to integrate the callers’ mental health provider into treatment: In the first coaching call, participants were asked about a mental health or other provider who could be contacted about the participant’s intention to quit tobacco. For
participants who were able to provide contact information (and gave consent), a standardized letter was sent to the provider. The letter contained information about quitting tobacco and tips for how the provider could support the participant in their quit efforts, including advising providers to monitor psychotropic medication dosages in the event changes were needed after cessation.

**Participants and Recruitment**

TXQL callers who registered during the pilot period (August 8, 2016 through October 13, 2016) were eligible to be screened for the pilot if they were age 18 or older, English speakers, not pregnant, self-referred to the TXQL, enrolled via phone into the call program, and provided a valid phone number. These screening eligibility criteria were also applied to comparison groups. Callers who registered in the standard TXQL five-call program during the pre-pilot period (November 1, 2015 through August 7, 2016) and reported MHCs were included in the standard program with MHCs comparison group (group 1). Callers who registered during the pilot or pre-pilot periods and reported having no MHCs were included in the standard program with no MHCs comparison group (group 2). Callers who enrolled in the pilot were included in group 3. **Figure 1** presents the screening questions and triaged enrollment flow into the three groups.

During the pilot period to ensure that those with the most need of additional services were offered the pilot, a two-step screening process was implemented where all TXQL enrollees with bipolar disorder or schizophrenia were eligible for the pilot, but those reporting other disorders were only eligible if they reported concern that their MHC would interfere with cessation. More specifically, during the pilot period (August 8 through October 13, 2016), callers were asked at enrollment: “Have you ever been diagnosed with any mental health conditions: bipolar disorder, schizophrenia, anxiety disorder, depression, alcohol/drug abuse, or post-
traumatic stress disorder (PTSD)?” Those who said they had been diagnosed with bipolar disorder and/or schizophrenia (population 1) were offered the pilot program. Those who reported that they had not been diagnosed with bipolar disorder or schizophrenia, but had been diagnosed with one of the other disorders (population 2) were asked a second question: “Do you believe that your mental health condition will interfere with your ability to quit and/or stay quit?” If callers answered “yes” or “I don’t know”, they were offered the pilot program. The purpose of this second question was to triage services to those who needed them the most given that state budgets would not allow for all participants with a MHC to participate in the more costly program. Prior to the pilot period the mental health screening question was slightly different: “In the past year, have you ever been diagnosed with or received treatment for any of the following substance abuse, mental health conditions or emotional challenges: depression, anxiety disorder, bipolar disorder, post-traumatic stress disorder (PTSD), drug or alcohol abuse (SUD), schizophrenia?” Figure 1 illustrates the screening process for the pilot and the comparison groups.

Follow-Up Survey Administration

Follow-up outcome surveys were conducted via email and phone at 7 months post registration. Surveys were attempted on all TCBHP pilot registrants who met sample inclusion criteria. The outcome data for participants in the standard program was collected as part of a previously planned annual evaluation of the TXQL. Approval was obtained to use that already collected data for this analysis. The sample for the program outcome evaluation was selected using random sampling. Additionally, the state of Texas Department of Health requested that all LGBTQ callers be called (census) for outcome evaluation as this is a small priority population. Participants were included in the survey sample if they met the eligibility criteria above,
consented to evaluation follow-up, and completed at least one coaching call. Participants were included in the survey sample only once (regardless of the number of contacts with the TXQL), and only one participant was included per household.

**Measures**

Demographics and tobacco use data were collected at enrollment. The number of coaching calls, shipments of NRT, Web Coach® login days, and Text2Quit® utilization were recorded and examined as indicators of program engagement. Program satisfaction, last tobacco use, and NRT and prescription cessation medication use were assessed during the 7-month follow-up survey (in that order).

**Statistical analysis**

Chi-squares and Wilcoxon rank sum tests were conducted in SAS v9.4 (SAS Institute, Inc., Cary, NC, USA) to examine differences in caller characteristics and program engagement. Survey outcomes were weighted to account for differential sampling probabilities among standard program participants; due to the small pilot group size, statistical testing was not conducted on survey outcomes. Multiple imputation was performed using MICE in R v3.4 to impute missing responses to the question assessing MHC interference (which was not asked during the pre-pilot period; see Figure 1) and limit to a more appropriate comparison group. Outcomes analyses using multiply imputed data did not differ from analyses of observed data; results present observed (not imputed) data.

**RESULTS**

Caller characteristics and program engagement analyses include the 11,121 participants who met initial inclusion criteria and enrolled in the pilot (n=311), reported MHCs during the pre-pilot period (n=4933), or reported no MHCs (n=5877) (Figure 1). Outcomes analyses focus
on the subset of participants within each group who were included in the final survey sample and responded to the survey: enrolled in the pilot (n=79), reported MHCs during the pre-pilot period (n=223), or reported no MHCs (n=216).

Over half (53.5%) of participants who called the TXQL during the pilot period reported one or more MHCs. As shown in Figure 1, the first step of pilot eligibility screening placed 240 participants (45.3%) in population 1 (bipolar and/or schizophrenia; with or without other conditions), and 290 (54.7%) in population 2 (anxiety disorder, depression, alcohol/drug abuse, and/or PTSD; no diagnosis of bipolar or schizophrenia). In the second step of eligibility screening (population 2 only), 39% (n=113) of potential population 2 participants answered “yes” or “I don’t know” to the question about their MHC interfering with their ability to quit smoking. After screening, 353 participants were offered the pilot, and 311 (88.1%) accepted enrollment; pilot acceptance rates were similar between populations 1 and 2. Among pilot enrollees, 68% were in population 1 and 32% were in population 2. Co-morbidity was high in the pilot with 86% of population 1 participants also having other disorders such as depression, anxiety, PTSD, or alcohol/drug abuse in addition to bipolar disorder and/or schizophrenia and 61% of population 2 participants reporting two or more conditions. Half (50.5%) of pilot participants provided a mailing address for their healthcare provider (57.4% of population 1; 36.0% of population 2) and letters were sent to those providers.

Characteristics

As shown in Table 1, compared to callers without MHCs, callers with MHCs in the pilot or standard program were more likely to be female, Caucasian, Medicaid- or Medicare-insured (vs. uninsured or commercially insured), divorced or separated (vs. married or in a domestic partnership), smoke within 5 minutes of waking, smoke more cigarettes per day, and use
multiple tobacco types. Callers in both MHC groups were less likely to be heterosexual and have a formal high school degree or greater compared to those without MHC. In addition, pilot participants were less likely to be heterosexual and commercially insured, and more likely to be Caucasian and Medicaid-insured compared to callers with MHC in the standard program. Pilot participants were also far more likely to be diagnosed with bipolar disorder (59.2% vs. 35.5% \( p < .0001 \)) or schizophrenia (21.2% vs. 11.9%, \( p < .0001 \)), and rates of depression, anxiety, and PTSD were slightly higher in the pilot than in the MHC comparison group, likely due to the screening process for the pilot which offered the program to anyone with bipolar or schizophrenia. Pilot participants were also younger, on average, compared to the other two groups.

**Engagement**

Callers with MHCs in the pilot or standard program were more likely to complete at least one call compared to those without MHCs (85.5% and 84.3% vs. 79.0%, respectively, \( p < .0001 \)). Pilot participants completed nearly twice as many calls (mean = 3.4, \( SD = 2.4 \)) than those in either of the standard program comparison groups (with MHCs mean = 1.7, \( SD = 1.3 \); without MHCs mean = 1.5, \( SD = 1.0 \), \( p < .0001 \)). NRT was shipped to more pilot participants (80.1%) as compared to standard program participants with MHC (58.2%, \( p < .0001 \)) and without (38.9%, \( p < .0001 \)); standard program participants with MHC were also more likely to be shipped NRT compared to those without MHC (\( p < .0001 \)). More than one in five (22%) pilot participants received all three NRT shipments (four weeks of NRT in each shipment) offered, and 64% received at least one shipment of combination therapy. With regard to participation in the Text2Quit text messaging program, all groups were equally likely to enroll in the program, but callers with MHC(s) sent more keyword text messages requesting help, on average,
compared to those without MHC(s), and pilot participants sent more keywords compared to standard program participants with MHC(s).

**Seven-month outcomes**

Due to the small pilot participant group size, statistical testing was not conducted on 7-month survey outcomes; none of the following differences should be interpreted as statistically significant. Survey response rates were higher among participants in the standard program compared to the pilot. As expected, quit rates were highest among callers without MHCs (34.7% respondent 30-day quit rate, 95% CI: 28.7% - 40.7%). Pilot participants had numerically higher quit rates (30.4%, 95% CI: 20.5% - 41.8%) than those with MHC in the standard program (20.8%, 95% CI: 15.2% - 26.4%). Satisfaction and reported NRT use rates also were higher among pilot participants compared to the other two groups. Reported use of prescription cessation medications was similar between groups.

**DISCUSSION**

This project showed the feasibility of delivering a tailored intervention to quitline callers who report MHCs. The pilot sample had high levels of co-morbidity and serious mental illness, including a high rate of bipolar disorder (nearly 60%). This pilot showed that it is possible to recruit callers into a tailored program, as well as offer and deliver a more robust regimen of NRT and more coaching calls. In fact, those in the pilot of the tailored protocol received twice as many coaching calls as compared to standard program participants. Furthermore, nearly 90% of the pilot sample reported using NRT at follow up (80% were shipped NRT). These factors work synergistically: offering NRT helps initially engage smokers in treatment and multiple NRT shipments can increase engagement in follow-up calls, giving callers exposure to the behavioral
components of treatment. Further research is needed to determine if this increased exposure to treatment significantly impacts cessation rates.

Due to the small sample size for the outcome surveys, this project was not adequately powered to examine statistically significant differences in cessation outcomes. However, the pilot exhibited promising preliminary results for individuals with MHC with a 10 percentage point higher quit rate compared to the group of standard program participants with MHCs. The pilot group quit rate was still numerically lower than the quit rate for standard program participants with no MHC. A larger evaluation is needed to determine if the tailored treatment approach improves quit rates and to what degree.

One strength of this pilot is the scalability of the intervention. The Veterans Health Administration (VA) has piloted a specialized telephone treatment protocol for veterans referred by their mental health provider which included up to 10 specialized counseling calls and were supported in their quit attempts by their mental health providers. All patients received medication as prescribed by their VA providers. Participants who received the specialized protocol had better self-reported cessation rates at 6 months (18% vs. 12% intent-to-treat, \( p < .01 \)) as compared to a control condition where participants were told to call their state provided quitline.\(^{38}\) The protocol piloted in this VA study suggests promising outcomes for a well-tailored intervention, but is unlikely to be disseminated in state quitlines as it depends on integration with an in-person mental health clinic and requires medication to be prescribed by a provider. In contrast, the TCBHP protocol is scalable, requiring only bachelor’s level cessation specialists and with the ability to ship NRT directly to participants. Further, while integration with a mental health treatment is ideal, many quitline callers do not have such providers and requiring attendance at a clinic is a barrier to treatment for some. In the TCBHP pilot, communication with the mental
health provider was simplified and one-directional (quitline provides information to the provider) and having a mental health provider is not required for participation.

Since this pilot was completed in 2017, several state quitlines have implemented the TCBHP, and several more plan to implement the program in 2019. This dissemination will allow us to evaluate the relative effectiveness of the program on a larger scale.

The primary limitations of this study were the small sample size and low response rate to the 7-month follow-up survey. The low follow-up rates are typical of quitline settings where incentives are rarely offered for survey completion. There were a number of other methodological shortcomings reflecting the real-world nature of the pilot (e.g., differing screening questions, differing methods of calling participants) that would need to be rectified in a more rigorous evaluation of the treatment protocol. A more thorough investigation of the tailored treatment would also include randomization, bioverified quit outcomes, and more detailed information about actual use of quit medications. Contact with providers who received the letter would allow more conclusions to be drawn about the usefulness of that piece of the intervention. Furthermore, additional information about mental health treatment and psychotropic medication use would have allowed us to describe our sample in more detail.

In sum, delivering a tailored quitline protocol for those with behavioral health conditions appears feasible and acceptable to quitline callers and has promising results with regard to engagement and cessation that need to be confirmed in a larger study.
Declaration of Interests

All authors are employees of Optum, the owner of the Quit For Life tobacco cessation program.

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References

Table 1. Baseline Characteristics of Pilot Participants and Comparison Groups, Collected at Enrollment

<table>
<thead>
<tr>
<th>Baseline characteristic</th>
<th>Pilot Participants</th>
<th>Standard program participants with MHCs</th>
<th>Standard program participants with no MHCs</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% (n/N)</td>
<td>% (n/N)</td>
<td>% (n/N)</td>
<td></td>
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<tr>
<td>Mental health conditions</td>
<td></td>
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<tr>
<td>Bipolar Disorder</td>
<td>59.2% (184/311)</td>
<td>35.5% (1751/4933)</td>
<td>0.0% (0/5877)</td>
<td>&lt;.0001</td>
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<td>Schizophrenia</td>
<td>21.2% (66/311)</td>
<td>11.9% (585/4933)</td>
<td>0.0% (0/5877)</td>
<td>&lt;.0001</td>
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<td>Depression</td>
<td>75.6% (235/311)</td>
<td>70.1% (3460/4933)</td>
<td>0.0% (0/5877)</td>
<td>.04</td>
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<tr>
<td>Anxiety Disorder</td>
<td>70.4% (219/311)</td>
<td>60.9% (3003/4933)</td>
<td>0.0% (0/5877)</td>
<td>&lt;.001</td>
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<td>Post-Traumatic Stress Disorder</td>
<td>30.9% (96/311)</td>
<td>21.8% (1075/4933)</td>
<td>0.0% (0/5877)</td>
<td>&lt;.001</td>
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<tr>
<td>Substance Abuse Disorder</td>
<td>21.9% (68/311)</td>
<td>19.3% (954/4933)</td>
<td>0.0% (0/5877)</td>
<td>.28</td>
</tr>
<tr>
<td>2+ conditions (any)</td>
<td>78.5% (244/311)</td>
<td>62.9% (3104/4933)</td>
<td>0.0% (0/5877)</td>
<td>&lt;.0001</td>
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<tr>
<td>Bipolar and/or Schizophrenia + other condition(s)</td>
<td>58.5% (182/311)</td>
<td>33.1% (1635/4933)</td>
<td>0.0% (0/5877)</td>
<td>&lt;.001</td>
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<tr>
<td>Gender</td>
<td></td>
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</tr>
<tr>
<td>Female</td>
<td>71.4% a (222/311)</td>
<td>69.9% a (3446/4933)</td>
<td>54.9% b (3227/5877)</td>
<td>&lt;.0001</td>
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<tr>
<td>Age</td>
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<tr>
<td>Mean ± SD</td>
<td>44.9 ± 13.3</td>
<td>48.9 ± 13.1</td>
<td>49.0 ± 14.4</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Race</td>
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<tr>
<td>Caucasian (vs. other races)</td>
<td>73.4% a (224/305)</td>
<td>67.2% b (3228/4806)</td>
<td>58.9% c (3182/5404)</td>
<td>&lt;.0001</td>
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<td>Education</td>
<td></td>
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<tr>
<td>HS degree or greater (vs. GED or &lt; HS)</td>
<td>62.9% a (188/299)</td>
<td>66.8% a (3184/4765)</td>
<td>72.0% a (3868/5370)</td>
<td>&lt;.0001</td>
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<tr>
<td>Health insurance status</td>
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<tr>
<td>Commercial/private insurance</td>
<td>9.9% a (30/303)</td>
<td>16.8% a (805/4791)</td>
<td>26.7% b (1513/5673)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Medicaid</td>
<td>31.7% a (96/303)</td>
<td>26.3% b (1259/4791)</td>
<td>13.0% b (735/5673)</td>
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<td>Medicare</td>
<td>22.4% a (68/303)</td>
<td>24.3% a (1163/4791)</td>
<td>17.6% b (999/5673)</td>
<td></td>
</tr>
<tr>
<td>Uninsured</td>
<td>36.0% a (109/303)</td>
<td>32.6% a (1564/4791)</td>
<td>42.8% a (2426/5673)</td>
<td></td>
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<tr>
<td>Sexual orientation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterosexual (vs. other orientations)</td>
<td>87.6% a (254/290)</td>
<td>92.7% b (4325/4668)</td>
<td>95.7% a (5005/5228)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Marital status</td>
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<tr>
<td>Single</td>
<td>39.7% (120/302)</td>
<td>37.2% (1770/4755)</td>
<td>37.3% (2006/5376)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Divorced or separated</td>
<td>25.5% a (77/302)</td>
<td>27.8% a (1321/4755)</td>
<td>19.3% b (1036/5376)</td>
<td></td>
</tr>
<tr>
<td>Married or in domestic partnership</td>
<td>29.1% a (88/302)</td>
<td>26.2% b (1244/4755)</td>
<td>34.9% b (1878/5376)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>5.6% (17/302)</td>
<td>8.8% (420/4755)</td>
<td>8.5% (456/5376)</td>
<td></td>
</tr>
<tr>
<td>Tobacco history at enrollment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoke daily</td>
<td>92.6% (274/296)</td>
<td>94.9% (4467/4708)</td>
<td>95.5% (5096/5339)</td>
<td>.051</td>
</tr>
<tr>
<td>Smoke within 5 minutes of waking</td>
<td>58.1% a (173/298)</td>
<td>54.8% a (2613/4766)</td>
<td>43.2% a (2363/5471)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td></td>
<td>20.6 ± 12.7</td>
<td>19.3 ± 11.6</td>
<td>18.1 ± 10.8</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-------------</td>
<td>-------------</td>
<td>-------------</td>
<td>--------</td>
</tr>
<tr>
<td>Mean cigarettes/day ± SD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple tobacco types</td>
<td>7.4% a (23/311)</td>
<td>6.8% a (335/4933)</td>
<td>4.3% b (255/5877)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

Note. Responses of “refused”, “don’t know”, and “not collected” are excluded from characteristics analyses. Numbers that share a superscript do not significantly differ.

MHC = mental health condition; n = number of respondents; N = group denominator; HS = high school; GED = General Equivalency Diploma.

1 Multiple conditions reported; results might not add up to 100%.
Table 2. Program Engagement among Pilot Participants and Comparison Groups

<table>
<thead>
<tr>
<th>Program engagement metric</th>
<th>Pilot Participants</th>
<th>Standard program participants with MHCs</th>
<th>Standard program participants with no MHCs</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call completion</td>
<td>85.5%&lt;sup&gt;a&lt;/sup&gt; (266/311)</td>
<td>84.3%&lt;sup&gt;a&lt;/sup&gt; (4159/4933)</td>
<td>79.0%&lt;sup&gt;b&lt;/sup&gt; (4642/5877)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Mean call completion ± SD&lt;sup&gt;1&lt;/sup&gt;</td>
<td>3.4&lt;sup&gt;a&lt;/sup&gt; ± 2.4</td>
<td>1.7&lt;sup&gt;b&lt;/sup&gt; ± 1.3</td>
<td>1.5&lt;sup&gt;c&lt;/sup&gt; ± 1.0</td>
<td></td>
</tr>
<tr>
<td>NRT shipments</td>
<td>80.1%&lt;sup&gt;a&lt;/sup&gt; (249/311)</td>
<td>58.2%&lt;sup&gt;b&lt;/sup&gt; (2871/4933)</td>
<td>38.9%&lt;sup&gt;c&lt;/sup&gt; (2287/5877)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>1 shipment</td>
<td>40.5% (126/311)</td>
<td>58.1% (2867/4933)</td>
<td>38.9% (2283/5877)</td>
<td></td>
</tr>
<tr>
<td>2 shipments</td>
<td>17.4% (54/311)</td>
<td>0.1% (4/4933)</td>
<td>0.1% (4/5877)</td>
<td>--</td>
</tr>
<tr>
<td>3 shipments</td>
<td>22.2% (69/311)</td>
<td>0.0% (0/4933)</td>
<td>0.0% (0/5877)</td>
<td>--</td>
</tr>
<tr>
<td>1+ shipments of combination therapy</td>
<td>64.3% (200/311)</td>
<td>0.0% (0/4933)</td>
<td>0.0% (0/5877)</td>
<td>--</td>
</tr>
<tr>
<td>Text messaging</td>
<td>40.8% (127/311)</td>
<td>38.4% (1894/4933)</td>
<td>36.8% (2161/5877)</td>
<td>.11</td>
</tr>
<tr>
<td>Mean Text2Quit key words ± SD&lt;sup&gt;1&lt;/sup&gt;</td>
<td>3.1&lt;sup&gt;a&lt;/sup&gt; ± 4.3</td>
<td>2.8&lt;sup&gt;b&lt;/sup&gt; ± 7.6</td>
<td>1.8&lt;sup&gt;c&lt;/sup&gt; ± 2.8</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Online engagement</td>
<td>52.7% (164/311)</td>
<td>47.9%&lt;sup&gt;a&lt;/sup&gt; (2362/4933)</td>
<td>50.8%&lt;sup&gt;b&lt;/sup&gt; (2985/5877)</td>
<td>.006</td>
</tr>
<tr>
<td>Mean Web Coach® login days ± SD&lt;sup&gt;1&lt;/sup&gt;</td>
<td>4.1 ± 7.8</td>
<td>3.3 ± 7.2</td>
<td>2.5&lt;sup&gt;b&lt;/sup&gt; ± 4.8</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

Note. Numbers that share a superscript do not significantly differ.

MHC = mental health condition; n = number of respondents; N = group denominator; NRT = nicotine replacement therapy.

<sup>1</sup> Mean ± SD call completion, Text2Quit key words, and Web Coach® login days reported among those who completed a call, enrolled in Text2Quit, or enrolled in Web Coach.
Table 3. Weighted Survey Outcomes at 7 Months Post Enrollment among Pilot Participants and Comparison Groups

<table>
<thead>
<tr>
<th>7-month survey outcome (weighted)</th>
<th>Pilot Participants % (n/N)</th>
<th>Standard program participants with MHCs % (n/N)</th>
<th>Standard program participants with no MHCs % (n/N)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response rate</td>
<td>35.0% (79/226)</td>
<td>43.1% (206/477)</td>
<td>40.6% (245/603)</td>
<td>--</td>
</tr>
<tr>
<td>Satisfaction rate</td>
<td>94.9% (74/78)</td>
<td>88.0% (178/202)</td>
<td>86.3% (203/235)</td>
<td>--</td>
</tr>
<tr>
<td>Respondent quit rate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-day respondent quit rate</td>
<td>30.4% (24/79)</td>
<td>20.8% (42/200)</td>
<td>34.7% (84/242)</td>
<td>--</td>
</tr>
<tr>
<td>Respondent 95% Confidence Interval</td>
<td>20.5% - 41.8%</td>
<td>15.2% - 26.4%</td>
<td>28.7% - 40.7%</td>
<td>--</td>
</tr>
<tr>
<td>Intent-to-treat quit rate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-day intent-to-treat quit rate</td>
<td>10.6% (24/226)</td>
<td>8.7% (42/477)</td>
<td>13.9% (84/603)</td>
<td>--</td>
</tr>
<tr>
<td>Intent-to-treat 95% Confidence Interval</td>
<td>6.9% - 15.4%</td>
<td>6.2% - 11.2%</td>
<td>11.1% - 16.7%</td>
<td>--</td>
</tr>
<tr>
<td>Cessation medication use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reported NRT use</td>
<td>88.5% (69/78)</td>
<td>62.4% (127/203)</td>
<td>57.5% (140/243)</td>
<td>--</td>
</tr>
<tr>
<td>Reported Rx use</td>
<td>10.3% (8/78)</td>
<td>10.8% (22/203)</td>
<td>9.9% (24/243)</td>
<td>--</td>
</tr>
</tbody>
</table>

Note. Responses of “refused”, “don’t know”, and “not collected” are excluded from 7-month survey outcome analyses (with the exception of response rate and intent-to-treat).

MHC = mental health condition; n = number of respondents; N = group denominator; NRT = nicotine replacement therapy; Rx = prescription cessation medication.

1 Survey outcomes were weighted to account for differential sampling probabilities among standard program participants; ns are approximate and will not match Figure 1.

2 Due to the small pilot group size, statistical testing was not conducted on survey outcomes.
TXQL multiple-call program enrollees who met the following criteria (n=11,438):
- English speakers entered program via inbound phone call
- Aged ≥18 years
- Not pregnant

Pre-pilot (Nov 1, 2015 – Aug 7, 2016) asked at enrollment: “In the past year, have you ever been
diagnosed with or received treatment for any of the following substance abuse, mental health
conditions or emotional challenges: Depression, Anxiety Disorder, Bipolar Disorder, Post-
Traumatic Stress Disorder (PTSD), Drug or Alcohol Abuse (SUD), Schizophrenia?” (n=10,363)

Pilot period (Aug 8 – Oct 13, 2016) asked at enrollment: “Have you ever been diagnosed
with any mental health conditions: Bipolar Disorder, Schizophrenia, Anxiety Disorder,
Depression Disorder, Alcohol/Drug Abuse, or Post-Traumatic Stress Disorder (PTSD)?”
(n=1,075)

EXCLUSIONS:
- Did not respond to MHC question: 53

Pre-Pilot reported no MHC(s) (n=5381)

Pilot period reported no MHC(s) (n=496)

EXCLUSIONS:
- Technology issue – screening not completed: 45

Population 1: Reported Bipolar and/or Schizophrenia, with or without additional conditions (n=240)

EXCLUSIONS:
- Completed survey after re-enrolling (in pilot): 9

Total reported no MHC(s) (n=5877); 52.8%

Sampled for TXQL standard evaluation via mix of random sampling and census (n=556)

Group 1: Standard program with MHC(s) (n=547)
- Lost to follow-up (n=324)
- Responded to 7-month survey (n=223; 40.8%)

Pilot participants (n=311)

Acceptance rates:
- Population 1: 87.9% (211/240)
- Population 2: 88.5% (100/113)

Sampled for TXQL standard evaluation via mix of random sampling and census (n=545)

Group 2: Standard program with NO MHC(s) (n=545)
- Lost to follow-up (n=329)
- Responded to 7-month survey (n=216; 39.6%)

EXCLUSIONS:
- Duplicate enrollment: 33
- 0 calls completed: 41
- Did not consent to follow-up: 8
- Requested no further contact: 3

Sampled for pilot evaluation via census (n=226)

Group 3: Pilot program (n=226)
- Lost to follow-up (n=147)
- Responded to 7-month survey (n=79; 35.0%)

Offered Pilot (n=353)

“yes” or “I don’t know” (n=113)

“no” or “refused” (n=177)

Declined pilot (n=42)

Figure 1. Quitline pilot study screening and enrollment flow