Proactive tobacco treatment for individuals with and without a mental health diagnosis: secondary analysis of a pragmatic randomized controlled trial

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Abstract

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INTRODUCTION—Individuals with (vs. without) mental illness use tobacco at higher rates and have more difficulty quitting. Treatment models for smokers with mental illness are needed.

METHODS—This secondary analysis of the Victory Over Tobacco study [a pragmatic randomized clinical trial (N=5123) conducted in 2009–2011 of Proactive Care (proactive outreach plus connection to smoking cessation services) vs. Usual Care] tests the effectiveness of treatment assignment in participants with and without a mental health diagnosis on population- level, 6 month prolonged abstinence at one year follow-up.

RESULTS—Analyses conducted in 2015–6 found that there was no interaction between treatment group and mental health group on abstinence (F(1,3300=1.12, p=0.29)). Analyses stratified by mental health group showed that those without mental illness, assigned to Proactive Care, had a significantly higher population- level abstinence rate than those assigned to usual care (OR=1.40, 95% CI=1.17–1.67); in those with mental illness, assignment to Proactive Care produced a non-significant increase in abstinence compared to Usual Care (OR=1.18, 95% CI=0.98–1.41). Those with mental illness reported more medical visits, cessation advice and treatment (p<0.001), similar levels of abstinence motivation (p>0.05), but lower abstinence self-efficacy (p<0.001).

CONCLUSIONS—Those with a mental health diagnosis benefitted less from proactive outreach regarding tobacco use. VA primary care patients with mental illness may not need additional outreach because they are connected to cessation resources during medical appointments. This group may also require more intensive cessation interventions targeting self-efficacy to improve cessation rates. Clinicaltrials.gov registration # NCT00608426.

Keywords

Introduction

Individuals with mental health diagnoses (MHDX) smoke at higher rates and have more difficulty quitting than those without (Bowden, Miller, & Hiller, 2011; Cook et al., 2014; Smith, Mazure, & McKee, 2014). Despite reporting similar motivation to quit (Siru, Hulse, & Tait, 2009), and making a comparable number of quit attempts, the prevalence of smoking in those with MHDX remains steady while the prevalence among those without MHDX declines (Cook et al., 2014). Steady prevalence rates suggest less success in quit attempts (McClave, McKnight-Eily, Davis, & Dube, 2010; Steinberg, Williams, & Yunqing, 2015). Identification and application of effective treatment models are necessary to ameliorate this growing health disparity.

Current treatment delivery models for tobacco cessation either rely on providers to address tobacco during already time-pressed visits, or on smokers to request treatment. These models may be particularly ineffective for smokers with MHDX as mental health providers have among the lowest levels of intervention around tobacco use of any healthcare providers (Prochaska, 2010; Rogers et al., 2016).

Social cognitive theory can help explain why smokers with MHDX may not be receiving tobacco treatment (Bandura, 1986). This theory emphasizes an interaction between the social environment and cognitive factors on behavioral outcomes. For example, characteristics of the medical system (such as provider time and expectations) affect whether and how tobacco cessation treatment is offered. The impact of these factors will be affected by patients' attitudes toward medical care, trust in providers, and motivation to quit. Proactive intervention (proactively offering all smokers tobacco cessation treatment and coordinating connections to treatment) addresses this environmental factor of the medical system by reaching out to all smokers and addresses barriers by providing care outside of the medical encounter. This may be a more successful treatment model for smokers with a MHDX.

The current study tests the effectiveness of a proactive tobacco cessation program (proactive mail and telephone outreach plus referral to telephone or in person cessation services) for VA primary care patients (vs. usual care) among individuals with MHDX vs. those without. We hypothesize that proactive treatment will be effective in both those with and without MHDX. We explore potential explanatory variables for possible differential treatment effectiveness including motivation, self-efficacy and provider intervention.

Methods

This study is a secondary data analysis of a pragmatic randomized controlled clinical trial (Fu et al., 2012; Fu et al., 2014) of proactive tobacco cessation treatment compared to usual care on 6 month prolonged abstinence at 1 year follow-up. Study methods have been published (Fu et al., 2012; Fu et al., 2014).

Study Sample

Participants (N=5123) were recruited from four VA medical centers. Inclusion criteria were: current smoker, age 18–80 years old, identified through the VA's Electronic Medical Record Health Factors Dataset. Exclusion criteria included having an ICD 9 diagnosis of dementia, completing more than 10 mental health visits in the past year, receiving care in a VA satellite clinic, and not having valid contact information. The study was approved by the participating sites' institutional review boards.

Procedure

Identified participants were randomly assigned to a treatment group. All participants were asked to complete a mailed baseline and a 1 year follow-up survey (follow-up response rates: 69% no mental illness, 63% mental illness). Data was also abstracted from VA administrative databases.

Tobacco Cessation Treatments—Participants in the Proactive Care condition received proactive outreach (mailed materials followed by telephone outreach) offering tobacco cessation treatment (in-person counseling, telephone counseling [7-call protocol] and pharmacotherapy). Usual care received normal VA care (the VA care adheres to national guidelines including: annual screening for tobacco use; advising all tobacco users to stop

using; and offering medications, counseling, and referral for ongoing cessation counseling. Access to these resources was not facilitated by the study team in the Usual Care group).

Measures

Demographic variables—Educational attainment was assessed during the baseline survey. Additionally, age, race, ethnicity, sex and comorbid conditions (including mental health diagnoses, ICD-9 codes) were extracted from VA administrative databases for the year prior to the baseline survey. A dichotomous MHDX variable was computed aggregating all measured mental health diagnostic codes.

Smoking History—A smoking history questionnaire was administered at baseline and included the Fagerström Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker, & Fagerström, 1991). Provider delivery of smoking cessation care was measured using patient report of tobacco intervention (Davis, 1997).

Readiness to quit—Readiness to quit was measured during the baseline survey using the Abram's Readiness to Ladder (Abrams DB, 2003), a 10-point, single item scale.

Self-efficacy—Self-efficacy was measured using two measures of self-efficacy to quit. The first measures confidence to quit on a 0–5 Likert scale in a single item (Baldwin et al., 2006). The second measures three aspects of situational self-efficacy on a 7-point Likert scale: Emotional, Social, and Skill.

Treatment outcomes—The primary outcome is self-reported 6 months of prolonged abstinence preceding the 1 year follow-up survey.

Statistical analysis

All analyses were completed using SAS/STAT software, version 9.2 (SAS Institute Inc). Participants with (N=2,465) and without (N=2,658) a chart-documented mental health diagnosis were compared on demographic characteristics, motivation and treatment utilization using weighted, stratified F tests, Wilcoxon rank-sum (Z approximation), and weighted , stratified Wald χ^2 tests as appropriate for variable type (see Table 1). The weights were inverses of the sampling proportions from each study site. To determine the effectiveness of the proactive tobacco cessation program (vs. usual care) between MHDX and noMHDX groups, we conducted a multivariable logistic regression and assessed the interaction between treatment group and MHDX group. Because understanding how the proactive treatment performed in those with and without MHDX is the main aim of this paper, we also conducted logistic regressions stratified by MHDX group. Control variables included study site and baseline variables unbalanced between treatment arms. Logistic regression models were run twice, using a complete case analysis and a not-missing-at-random (NMAR) mechanism such that nonresponse may depend on unobserved smoking status of the subject (e.g., smokers may have been less likely to complete the follow-up survey). To assess this supposition, we modeled the joint distribution of abstinence status and response status for the logistic regressions using an expectation maximization (EM) algorithm to find maximum likelihood estimators (Ibrahim, Chen, & Lipsitz, 2001). If the

second set of logistic regression models were to include missing baseline survey covariates, multiple imputation methods were applied first yielding five imputed data sets that included imputed values for the missing baseline survey covariates and then the NMAR method was applied.

Results

Demographics

Forty eight percent of the sample had a MHDX. The most common diagnoses were depression (46%) and substance use disorder (44%). Participants with a MHDX were more likely to be female and non-white than those without. Participants with a MHDX were more nicotine dependent than those without. (See Tables 1 & 2).

Treatment group performance by MHDX

Prolonged abstinence rates did not significantly differ between those with and without a MHDX (F(1,3301=2.6, p=.11) using complete case analysis. There was also no significant interaction between treatment group and MHDX F(1,3300=1.12, p=.29) using complete case analysis. Models using the likelihood-based NMAR methods yielded similar results.

In the analyses stratified by MHDX, we controlled for covariates that were not balanced by treatment group (noMHDX control variable: Situational Self-Efficacy Emotions scale; MHDX control variable: number of visits in which provider recommended cessation). Using both analytical strategies, assignment to the Proactive Care group produced higher prolonged abstinence rates than Usual Care for those without a MHDX (complete case: OR=2.05, 95% CI=1.43–2.93; NMAR: OR=1.40, 95% CI=1.17–1.67) and smaller effects on abstinence in those with a MHDX (complete case: OR=1.20, 95% CI=0.81–1.78; NMAR: OR=1.18, 95% CI=0.98–1.41). (See Table 3).

Self efficacy and motivation to quit

Individuals with a MHDX reported similar motivation to quit smoking (Z=0.30, p=.76) as those without. Similarly, individuals with a MHDX expressed similar levels of confidence to quit as those without (Z= −1.22, p=.22). Individuals with a MHDX reported lower self-efficacy to quit on the Situational Self-efficacy Emotions scale (Z= −6.56, p<0.001), the Situational Self-efficacy Situations Scale (Z= −5.77, p<0.001) and the Skill Self-efficacy scale (Z= −4.48, p<0.001). (See Table 2).

Provider tobacco interventions

Participants with a MHDX reported more visits to medical providers (see Table 2; F(2, 2938)=32.49, p<.001). Among participants with at least one visit in the past year, those with a MHDX reported that providers recommended smoking cessation more often than those without (F(4, 2910)=16.09, p<0.001). Similarly, individuals with a MHDX reported more provider recommendations for non-medication (e.g., counseling; F(4, 2922)=10.04, p<0.001) and medication (F(4, 2896)=9.35, p<0.001) cessation treatments (See Table 2). These differences remained significant even after controlling for the number of medical visits in the past year.

Discussion

Results from the current study demonstrated that proactive tobacco cessation treatment promoted cessation both for those with a MHDX and those without. Though this intervention had a moderate effect (2% improvement in cessation rates) on smokers with a MHDX that is significant from a public health perspective, it was insufficient to produce a large population-level change in this difficult to treat group. Our proactive intervention involved a single episode of care and was of moderate intensity, in that, like most primary care interventions, it involved connecting smokers to cessation resources. More intensive interventions using a chronic care approach may be necessary to improve cessation rates in those with MHDX (Williams, Steinberg, Kenefake, & Burke, 2016).

Consistent with Social Cognitive Theory, the environment in VA medical system could promote cessation among smokers with MHDX in a way not seen in research in civilians. Because smokers with MHDX reported more contact with VA medical providers, the VA medical system, which requires regular provider intervention around tobacco use, may have attenuated the benefit of a moderate-intensity tobacco cessation intervention such as connection to cessation services. This is supported by findings that those with a MHDX reported more provider cessation assistance and had higher quit rates during usual care than those without a MHDX.

Consistent with Social Cognitive Theory, cognitive factors may have promoted cessation or diminished the effects of the proactive intervention among smokers with MHDX. Consistent with previous work (Aubin, Rollema, Svensson, & Winterer, 2012; Bowden et al., 2011; Siru et al., 2009), we found that smokers with MHDX reported similar motivation to quit as those without, suggesting that lack of motivation did not explain the smaller benefit of the intervention. However, consistent with previous research (Clyde, Tulloch, Reid, Els, & Pipe, 2015), smokers with MHDX reported lower skill self-efficacy to quit including self-efficacy not to smoke when experiencing negative emotions, in social situations, and to advocate for and coach oneself to remain abstinent. Tailored interventions that focus on improving skills to overcome barriers to quit may be more effective in smokers with MHDX. For example, a recent study found that for VA patients in mental health clinics, multi-session counseling tailored to Veterans with MHDX, delivered by study staff, was more effective than transfer to the state quitline (Rogers et al., 2016).

Limitations

Interpretations of findings should keep in mind that the MHDX group in this study was intended to represent mental health patients seen in a primary care setting and does not provide information on smokers with more severe mental illness. There is an ongoing study of proactive outreach to patients followed in VA Mental Health Clinics (Rogers et al., 2014). In addition, the current study was conducted in a sample of predominantly male Veterans. While we did not find evidence that the interaction between treatment group and MHDX was moderated by gender, these findings should be replicated in civilian samples and among women.

Conclusions

The current study represents one of the first studies to test the differential effect of a pragmatic, behavioral intervention for smokers with and without a MHDX. A moderate-intensity intervention of proactive outreach to connect smokers to cessation resources was effective for those with and without MHDX. Effect sizes were larger in those without MHDX. Additional marginal benefit in this highly engaged population with high levels of nicotine dependence will require tailored and intensive longitudinal interventions (Hitsman, Moss, Montoya, & George, 2009; Williams et al., 2016).

Acknowledgments

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Highlights

- Proactive outreach is less effective for smokers with psychiatric diagnoses.

- Smokers with psychiatric diagnoses are motivated but lack self-efficacy to quit.

- Smokers with psychiatric diagnoses receive provider intervention about smoking.

- Intensive cessation interventions are needed for smokers with mental illness.

Demographics and smoking variables by mental illness group

Table 1

Measure	All	Mental Health Diagnosis	No Mental Health Diagnosis	p
Sample				
All randomized subjects	N=5123	N=2465	N=2658	
Male N(%)	4830 (94)	2298 (93)	2532 (95)	<0.001
Race N(%)				<0.001
White	2970 (65)	1360 (62)	1610 (67)	
Black	1418 (23)	729 (25)	689 (21)	
Other	735 (13)	376 (13)	359 (12)	
Age Med [IQR]	58 [13]	56 [13]	60 [13]	<0.001
Responded to baseline survey	N=3327	N=1571	N=1756	
>High School education N(%)	1667 (51)	778 (51)	889 (51)	0.96
Cigarettes per day N(%)				0.02
10	1153 (32)	529 (31)	624 (33)	
11–20	1413 (45)	650 (44)	763 (46)	
20	701 (23)	358 (25)	343 (21)	
Time to first cigarette N(%)				<0.001
5 minutes	698 (21)	397 (26)	301 (17)	
6–30 minutes	1705 (53)	804 (53)	901 (53)	
31 minutes	894 (26)	354 (21)	540 (30)	
Readiness to Quit Med[IQR]	4.9 [3.3]	4.9 [3.1]	4.9 [3.3]	0.76
Situational Self-efficacy- Emotions Med[IQR]	−0.6 [2.9]	−1.0 [2.7]	−0.3 [2.9]	<0.001
Situational Self-Efficacy- Social Situations Med[IQR]	−0.3 [2.9]	−0.4 [2.9]	−0.2 [3.0]	<0.001
Skill Self-efficacy Med[IQR]	0.1 [2.3]	0.0 [2.3]	0.3 [2.2]	<0.001
Confidence to quit Med[IQR]	1.9 [2.3]	1.9 [2.4]	2.0 [2.2]	0.22
# VA medical visits past year N(%)				<0.001
None	39 (1.4)	17 (1.4)	22 (1.5)	
1	391 (15)	108 (9)	283 (20)	
>1	2513 (84)	1229 (90)	1284 (79)	
VA provider advised to quit past year N(%)				<0.001

Sample	All	Mental Health Diagnosis	No Mental Health Diagnosis	p
Measure				
Never	227 (8)	111 (8)	116 (7)	
1 time	583 (20)	216 (16)	367 (24)	
2–4 times	1544 (50)	689 (48)	855 (52)	
5–9 times	429 (13)	243 (16)	186 (10)	
10 times	302 (9)	173 (12)	129 (7)	
VA provider recommended medication N(%)				<0.001
Never	916 (30)	425 (31)	491 (30)	
1 time	769 (27)	305 (22)	464 (30)	
2–4 times	1044 (33)	501 (35)	543 (32)	
5–9 times	222 (7)	97 (5)		
10 times	116 (3)	47 (3)		
VA provider recommended non-medication ways to quit N(%)				<0.001
Never	803 (27)	353 (25)	450 (28)	
1 time	735 (25)	292 (21)	443 (28)	
2–4 times	1131 (35)	563 (38)	568 (33)	
5–9 times	272 (8)	147 (9)	125 (7)	
10 times	156 (5)	86 (6)	70 (4)	

Notes: 1) Bold font indicates statistical significance. 2) For data from the medical record: Mental Health Diagnosis was abstracted from the medical record, all medical record variables are based on administrative records and are complete for N=5,123. For data from the baseline survey: Number of observed values for each of these measures range from 2943 (# VA medical visits) to 3297 (time to first cigarette) due to item missingness. 3) The intra-block comparisons are reported due to the randomized block (facility) design (Domain Analysis). 4) Observed counts, yet weighted column proportions are reported, otherwise weighted median [IQR] are reported.

Table 2

Effect of treatment group on 1 year prolonged smoking abstinence by treatment group

Analysis	Mental Health Diagnosis Group	Variable	OR	95% CI
Complete case (n=2365)	Mental Health Diagnosis (n=1100)	Treatment group	1.20	0.81–1.78
	No Mental Health Diagnosis (n=1265)	Treatment group	**2.05**	1.43–2.93
All cases (n=5123)	Mental Health Diagnosis (n=2465)	Treatment group	1.18	0.98–1.41
	No Mental Health Diagnosis (n=2658)		**1.40**	1.17–1.67

Note: Treatment group: 1= Proactive 0=Usual Care. Bold font indicates statistical significance. The complete case analysis utilized only participants who responded to the follow-up survey. The all case analysis utilized multiple imputation and non-ignorable missingness methods to account for missing values. All analyses controlled for study site and unbalanced by treatment group covariates which have missing values.