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Short Communication

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

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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.

## ARTICLE INFO

*Keywords:*
Tobacco use cessation
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## ABSTRACT

*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.

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## 1. 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.

## 2. Methods

This study is a secondary data analysis of a pragmatic randomized controlled clinical trial (Fu et al., 2012, 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, 2014).

### 2.1. 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 > 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.

### 2.2. 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.

#### 2.2.1. 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).

### 2.3. Measures

#### 2.3.1. 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.

#### 2.3.2. 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).

#### 2.3.3. Readiness to quit

Readiness to quit was measured during the baseline survey using the Abrams Readiness to Ladder (Abrams et al., 2003), a 10-point, single item scale.

#### 2.3.4. 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.

#### 2.3.5. Treatment outcomes

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

### 2.4. Statistical analysis

All analyses were completed using SAS/STAT software, version 9.2 (SAS Institute Inc). Participants with (N = 2465) and without (N = 2658) 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 $\chi^2$ 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