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## Increased Self-efficacy to Quit and Perceived Control over Withdrawal Symptoms Predict Smoking Cessation Following Nicotine Dependence Treatment

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## Abstract

**Aim**—To examine changes in nicotine withdrawal, nicotine craving, self-efficacy to quit smoking, and perceived control over withdrawal symptoms as predictors of smoking cessation following behavioral counseling and nicotine replacement therapy in a sample of smokers.

**Design and Setting**—Data were ascertained from a randomized effectiveness trial comparing nicotine patch to nicotine lozenge. Predictors of smoking cessation were assessed at baseline and five weeks post-baseline, and 24-hour point prevalence abstinence, biochemically confirmed, was assessed at the end-of-treatment (week 15) and 6-months after a target quit date (week 27).

**Participants**—642 treatment-seeking smokers randomized to twelve weeks of nicotine patch or nicotine lozenge.

**Findings**—Participants who showed a greater increase in self-efficacy to quit smoking (OR = 1.09, 95% CI: 1.02-1.16, p = .01) and perceived control over withdrawal symptoms (OR = 1.02, 95% CI: 1.00-1.04, p = .05) were significantly more likely to have quit smoking at week 15. Participants who showed a greater increase in self-efficacy to quit smoking (OR = 1.04, 95% CI: 1.01-1.06, p = .01)

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DECLARATIONS OF INTEREST

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were significantly more likely to have quit smoking at week 27. Changes in withdrawal symptoms and craving were not related to week 15 or week 27 abstinence rates.

**Conclusions**—The results highlight two relatively under-studied potential psychological predictors of abstinence following treatment for nicotine dependence. Behavioral counseling interventions to promote smoking cessation should help smokers develop confidence in their ability to quit smoking and increase their sense of control over withdrawal symptoms to increase their chances for cessation.

## INTRODUCTION

One reason for the progress made over the past several decades in reducing the rate of smoking in the United States, and elsewhere, has been the development and increased use of behavioral and pharmacological treatments for nicotine dependence [1]. While nicotine replacement therapies (NRT) remain extremely popular among smokers trying to quit, unfortunately only a minority of smokers (about 1 in 5 smokers) who use NRT are able to quit smoking successfully [2]. Consequently, nicotine dependence remains a critical public health issue, with prevalence rates over the past several years holding steady around 20% [3]. Identifying factors related to the ability to quit smoking can help inform efforts to refine treatment programs in order to increase the probability of successful cessation and lead to further reductions in the overall rates of smoking.

Previous studies have associated a range of demographic (e.g., age, gender) and smokingrelated (e.g., level of nicotine dependence) variables with the ability to quit smoking [4-6]. In addition, a range of psychological variables have been linked with the ability to quit smoking, including quit motivation [7] and current symptoms of depression [8] and, most commonly, nicotine withdrawal symptoms [9] and urges to smoke (i.e., craving; [10-12]). While these findings help researchers and clinicians to develop and evaluate clinical interventions for nicotine dependence, assessment of relatively novel predictors of smoking cessation following treatment is a priority for further advancements in this area.

There is a rich literature that documents the importance of a sense of personal control in determining adaptive behavioral responses in the context of health and illness [13] and this variable is a central determinant of adaptive responding within well-established models of health behavior change such as the Theory of Planned Behavior [14]. However, perception of control over abstinence-induced symptoms has not been evaluated as a predictor of success in smoking cessation clinical trials. Likewise, self-efficacy to quit smoking has been related to the ability to quit smoking in descriptive studies [15], but only recently has this variable been evaluated as a specific predictor of treatment outcome in the context of smoking cessation trials [16].

Thus, in this study, data from a randomized Phase IV effectiveness clinical trial comparing nicotine patch to nicotine lozenge were used to examine predictors of post-treatment cessation. The primary results from this trial found no significant effect of NRT type on cessation outcomes [17]. In addition to the prospective design of this study, the data from this trial were collected repeatedly during the treatment phase to permit evaluation of initial changes in these variables as predictors of cessation outcomes. Further, consistent with an effectiveness trial design (vs. an efficacy trial), the inclusion and exclusion criteria were limited, thereby facilitating the inclusion of a sample that represents smokers from the community or in the "real-world" who do not typically have access to clinical trials, rather than smokers seen in the context of well-controlled clinical trials. An increased understanding of predictors of cessation outcomes in the context effectiveness studies may help further refine interventions designed to treat nicotine dependence.

## METHODS

#### Study Design

Details of this clinical trial are published elsewhere [17]. To summarize, data for this study were from a randomized Phase IV effectiveness clinical trial that was coordinated by the National Cancer Institute's Community Clinical Oncology Program, which conducts cancer treatment and prevention trials in community settings, thereby bringing potentially advanced interventions to communities that would not typically have access to such treatments. In this trial, treatment-seeking smokers from 13 sites across the US were enrolled and randomized to receive 12 weeks of either transdermal nicotine patches (Nicoderm CQ) or nicotine lozenge (COMMIT) open-label. All participants received five individual smoking cessation behavioral counseling sessions based on clinical treatment guidelines [1]. Data were collected at the time of enrollment (baseline, week 1), at a target quit date (TQD; week 3) when NRT was initiated, at week 5, at the end-of-treatment (week 15), and at 6-months post-TQD (week 27).

#### Participants

To be eligible, participants had to be adults (age 18 or older) who reported smoking, on average, 10 cigarettes per day or more. Since this was an effectiveness trial, the exclusion criteria were minimized. However, for safety reasons, participants were excluded if they had a medical or medication contraindication for using NRT (e.g., allergy to latex, uncontrolled high blood pressure). Over 4 years, 651 individuals were randomized; 9 individuals either withdrew from the study prior to treatment or were found to be ineligible after randomization and were removed from the intent-to-treat (ITT) sample. The final ITT sample was 642 (321/arm). Notably, more than 35% of the sample were racial/ethnic minorities, including 12% Hispanic/Latino and 20% African American, about one-third of the sample indicated earning less than 330,000 per year, and about one-third of the sample reported having a high school diploma or less. Further, the mean number of cigarettes smoked per day reported by participants was 20.3 (SD = 9.1).

#### Measures

**Demographic Variables**—A standard measure to collect demographic information was administered (e.g., age, gender, race).

**Smoking Variables**—A standard measure to collect smoking-related information was administered (e.g., cigarettes per day). This measure included the 6-item Fagerström Test for Nicotine Dependence (FTND; [18]) to assess level of nicotine dependence, which classified smokers on a scale from 1 (very low) to 5 (very high).

**Withdrawal**—The 15-item Shiffman-Jarvik Withdrawal Scale [19] was used to assess nicotine withdrawal symptoms. Each item is scored on a Likert-type scale, from 1 = definitely not to 7 = definitely (e.g., "if you could smoke freely, would you like a cigarette this minute?"). An overall score was computed to represent level of current symptoms of nicotine withdrawal.

**Cravings**—The 10-item short-form of the Questionnaire of Smoking Urges (QSU; [20]) was used to assess craving for nicotine. Using a Likert-type scale, with scores ranging from 1 = strongly disagree to 7 = strongly agree, respondents indicated feelings toward items such as: "I am not missing smoking right now" and "my desire to smoke seems overpowering". An overall cravings score was computed by summing the scale items to represent current level of nicotine craving.

**Perceived Control Over Withdrawal Symptoms**—A 4-item survey designed for the clinical trial was used. Items were measured on a 5-point Likert-type scale, from 1 = strongly

disagree to 5 = strongly agree (i.e., "I feel like I have control over my feelings of withdrawal from cigarettes"; "I believe that I am capable of dealing adequately with withdrawal symptoms from smoking"; "I am able to manage the feelings of withdrawal from smoking that I experience"; "Although I may be experiencing withdrawal symptoms from not smoking, I am feeling like I can control and deal with them adequately"). A summed score was computed to represent greater perceived control by adding the responses to the four items (Chronbach's  $\alpha$  = .87).

**Self-efficacy to Quit Smoking**—The Smoking Self-efficacy Questionnaire (SSQ) was used to assess self-efficacy to quit smoking [21]. A total score was computed to represent greater self-efficacy by summing the 12 items of this scale, which has shown good reliability and validity in smoking cessation trials [21].

**Abstinence**—The primary outcome variable for this study (and the clinical trial) was carbon monoxide-confirmed 24-hour point prevalence abstinence at the EOT and 6-month assessments [22].

#### **Statistical Analyses**

Analysis of Variance (ANOVA) was used to examine the relationship between changes in withdrawal, craving, perceived control over withdrawal symptoms, and self-efficacy to quit smoking and week 15 and week 27 abstinence. A change score was created by subtracting the baseline values for these variables from the week 5 values for these variables so that a higher score on the change variables represented a greater increase in these variables from baseline to week 5 (e.g., a greater increase in perceived control over withdrawal symptoms over time). The change variables that were associated with week 15 and week 27 abstinence were included in separate multivariate logistic regression models for the two abstinence outcomes. Age, gender, and level of nicotine dependence were included as covariates in the regression models since these variables were associated with abstinence in the primary analyses of these data [17]. Variables in the regression models were evaluated in terms of odds ratios, 95% confidence intervals, and probability values. Participants with missing data on covariates, predictors, or outcomes were omitted from the analyses.

## RESULTS

#### Univariate Associations with Abstinence

Table 1 (top) shows the results of the ANOVAs for week 15 abstinence. At week 15, participants who were able to quit smoking showed a significantly greater increase from baseline to week 5 in perceived control over withdrawal symptoms and self-efficacy to quit smoking, compared to participants who relapsed to smoking by week 15. Table 1 (bottom) shows the results of the ANOVAs for week 27 abstinence. At week 27, participants who were able to quit smoking showed a significantly greater increase from baseline to week 5 in perceived control over withdrawal symptoms and self-efficacy to quit smoking, compared to participants who relapsed to smoking by week 27. Change in withdrawal and craving from baseline to week 5 did not predict smoking cessation at either week 15 or week 27. Consequently, only change in perceived control over withdrawal symptoms and change in self-efficacy to quit smoking were included in the multivariate regression models.

#### Multivariate Predictors of Abstinence

Table 2 shows the results of the multivariate logistic regression for week 15 (top) and week 27 (bottom) abstinence. Controlling for age, sex, and level of nicotine dependence, a greater increase in perceived control over withdrawal symptoms and self-efficacy to quit smoking from baseline to week 5 predicted a greater likelihood of abstinence at week 15. Likewise,

controlling for age, sex, and level of nicotine dependence, a greater increase in self-efficacy to quit smoking from baseline to week 5 predicted a greater likelihood of abstinence at week 27. Within both regression models, lower baseline level of nicotine dependence predicted a greater likelihood of abstinence.

## DISCUSSION

This study examined initial changes in nicotine withdrawal, craving, perceived control over withdrawal symptoms, and self-efficacy to quit smoking as predictors of end-of-treatment and long-term abstinence from smoking following a treatment program that provided behavioral counseling and NRT. The prospective nature of the study design, inclusion of community smokers as participants, and the evaluation of relatively novel predictors of abstinence provided an opportunity to enhance our understanding of predictors of response to treatment for nicotine dependence. Overall, while relatively more traditional predictors of treatment response, including changes in nicotine withdrawal and nicotine craving, did not predict treatment response, two less-studied predictors - perceived control over withdrawal symptoms and self-efficacy to quit smoking - did predict treatment response.

Trial participants who exhibited a greater increase in perceived control over withdrawal symptoms over the course of the first three weeks of treatment were significantly more likely to be abstinent at the end-of-treatment; this change, however, did not predict long-term abstinence assessed six months after the quit date. Nevertheless, to the best of our knowledge, this is the first study to link this variable with response to treatment for nicotine dependence. Further, this result converges with general theories of health behaviors [14] and an extensive literature that associates increased perceptions of control with more favorable health outcomes [13]. Moreover, this result suggests that behavioral strategies aimed at helping smokers increase their perceptions of control over abstinence-induced symptoms can help with at least the early phases of smoking cessation.

In addition, participants who exhibited a greater increase in self-efficacy to quit smoking over the course of the first two weeks of treatment were significantly more likely to be abstinent at the end-of-treatment, and this relationship persisted for the assessment of abstinence conducted six months following the target quit date. This result extends previous descriptive studies that have associated higher levels of self-efficacy to quit smoking with smoking cessation [15] and converges with recent studies that have associated higher self-efficacy to quit smoking with cessation [16]. The present study is unique in showing that it is not only higher levels of selfefficacy that predicts cessation but initial increases in this variable following cessation that predicts successful quitting; further, the present results are relatively unique in demonstrating the link between greater self-efficacy to quit smoking and long-term cessation outcomes. Thus, promoting a smoker's early sense of confidence in their ability to quit smoking seems important for enhancing the smoker's likelihood that they will successfully quit smoking following and long after treatment.

These results should be conceptualized in the context of study limitations. First, despite the prospective nature of the study, the analyses are correlational and, thus, no causal interpretations may be discerned from the results. Second, we examined a relatively small number of potential predictors of cessation outcomes in this sample. Given the complexities involved in conducting an effectiveness trial in a cooperative group, we were restricted in terms of the length of study surveys and frequency of measurement time-points. Third, since this was an effectiveness clinical trial, we emphasized external validity vs. internal validity, which is a greater concern in efficacy trials. This decision was based on the objective of examining the impact of these NRTs in a "real-world" setting and with smokers who otherwise would have limited access to such clinical trials. As such, the eligibility criteria were minimized, the

behavioral counseling was limited, and the treatments were unblinded. These factors may certainly have influenced the study results. Fourth, the change scores used to predict cessation may have been influenced by the participant's experience with the interventions and the participant's success or failure with cessation. Lastly, there was missing survey and outcome data from this trial. However, the amount of missing data in this trial is typical of community-based smoking cessation effectiveness trials [23].

Nevertheless, the present study findings augment our current understanding of factors that predict response to treatment for nicotine dependence. In particular, while controlling for demographic and smoking-related variables that predict treatment response, smokers who experience a greater increase in perceived control over withdrawal symptoms and quitting self-efficacy during the initial few weeks following a designated quit attempt are more likely to be successful with quitting smoking following treatment with behavioral counseling and NRT. Interventions for smokers that specifically target these two processes may show higher rates of treatment success, thereby contributing to further reductions in the overall prevalence rate of smoking.

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#### Table 1

Univariate Analysis of Predictors of Abstinence at Week 15 (Top) and Week 27 (Bottom)

	Week 15			
Predictor	Smokers M (SD)	Quitter M (SD)	F	р
Change in Withdrawal (df = $1, 290$ )	59.5 (21.3)	59.3 (21.8)	.003	.96
Change in Craving (df = 1, 299)	48.8 (21.1)	47.7 (16.4)	.229	.63
Change in Perceived Control (df = 1, 298)	15.8 (5.0)	17.7 (4.4)	12.39	< .01
Change in Self-efficacy (df = 1, 293)	50.9 (14.9)	55.7 (14.4)	6.64	.01
		Week 27		
Predictor	Smokers M (SD)	Quitter M (SD)	F	р
Change in Withdrawal (df = 1, 290)	59.3 (21.5)	59.9 (21.3)	.037	.85
Change in Craving (df = 1, 299)	48.3 (20.9)	49.3 (14.2)	.116	.73
Change in Perceived Control ( $df = 1, 298$ )	15.9 (5.2)	17.4 (3.7)	4.43	.04
Change in Self-efficacy (df = 1, 293)	51.2 (14.9)	57.3 (14.1)	7.95	.01

<u>Note</u>. M = mean; SD = Standard Deviation; p = probability; df = degrees of freedom.

### Table 2

Logistic Regression Predicting Abstinence at Week 15 (Top) and Week 27 (Bottom)

		Week 15	
Predictor	OR	95% CI	р
Age	1.02	1.00 - 1.05	.06
Sex <sup><i>a</i></sup>	1.44	.82 - 2.53	.21
Nicotine Dependence	0.55	.4470	<.001
Change in Perceived Control	1.09	1.02 - 1.16	.01
Change in Self-efficacy	1.02	1.00 - 1.04	.05
		Week 27	
Predictor	OR	95% CI	р
Age	1.01	.99 - 1.04	.44
Sex <sup><i>a</i></sup>	1.78	.95 - 3.34	.07
Nicotine Dependence	0.57	.4475	<.001
Change in Perceived Control	1.02	.95 - 1.10	.54
Change in Self-efficacy	1.04	1.01 - 1.06	.006

Note. OR = Odds Ratio; CI = Confidence Interval; p = Probability

<sup>*a*</sup>Male = 0 and Female = 1.