



Full length article

## Longitudinal changes in smoking abstinence symptoms and alternative reinforcers predict long-term smoking cessation outcomes



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### ARTICLE INFO

#### Article history:

Received 24 March 2016

Received in revised form 16 June 2016

Accepted 17 June 2016

Available online 25 June 2016

#### Keywords:

Smoking

Behavioral economics

Alternative reinforcers

Withdrawal

Craving

### ABSTRACT

**Background:** Transdermal nicotine, with behavioral counseling, is among the most popular approaches used to quit smoking. Yet, 6-month cessation rates rarely exceed 20–25%. Identifying factors associated with cessation success may help researchers and clinicians develop enhanced interventions that can improve quit rates. This study examined longitudinal changes in withdrawal, craving, depression and anxiety symptoms, and alternative reinforcers, from a baseline assessment to a 6-month outcome, as predictors of 6-month smoking cessation outcomes following 8 weeks of nicotine patch treatment and counseling.

**Methods:** A sample of 180 smokers, who completed an effectiveness trial that provided counseling and 8 weeks of 21 mg nicotine patches, was analyzed. Generalized estimating equations evaluated changes in withdrawal and craving, depression and anxiety symptoms, and alternative reinforcers over time, between participants who were smoking at 6-months and participants who were abstinent (confirmed with carbon monoxide) at 6-months. Multiple logistic regression assessed changes in these variables as predictors of relapse.

**Results:** Controlling for covariates associated with cessation (i.e., nicotine dependence, patch adherence, and rate of nicotine metabolism), participants who were abstinent at 6 months showed significantly lower craving and withdrawal and significantly higher substitute reinforcers from baseline to 6 months, vs. those who were smoking at 6 months ( $p < 0.001$ ). An increase in craving predicted relapse to smoking ( $p < 0.05$ ).

**Conclusions:** These results support continued efforts to strengthen interventions that reduce withdrawal and craving and the development of interventions to address alternative reinforcers in order to promote long-term smoking abstinence following nicotine patch treatment.

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## 1. Introduction

Owing to its availability as an over-the-counter medication, relative affordability, and favorable side effect profile, transdermal nicotine patches remain as one of the most popular methods that smokers use to make a quit attempt. Among smokers making a quit attempt, transdermal nicotine is the most popular form of nicotine replacement therapy and the second most popular form of pharmacotherapy, next to varenicline (Kasza et al., 2015). While popular, long-term cessation rates among users of the nicotine patch (with

counseling) rarely exceed 20–25% (Fiore et al., 2008). Identifying variables that enhance the effectiveness of transdermal nicotine by characterizing smokers who are successful in their attempt, vs. those who are unable to quit, may highlight novel treatment targets to boost treatment responsiveness.

Abstinence symptoms, emotional responses to quitting, and sources of alternative reinforcement are three such targets. Studies have documented the role that withdrawal symptoms and abstinence-induced craving have on relapse early in a quit attempt (al'Absi et al., 2007; Piasecki et al., 2000; Swan et al., 1996) and medications used to treat nicotine dependence are, in part, designed to reduce withdrawal and craving (Henningfield et al., 2009). However, even while abstinent, withdrawal and craving are highly variable and the impact of such variation across time on smoking

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abstinence is under-studied (Javitz et al., 2012). Likewise, elevated levels of depression and anxiety symptoms pre-cessation and early in the quit attempt have been linked to poorer smoking cessation outcomes at the end of treatment (Niaura et al., 2001; Leventhal et al., 2008, 2014; Kenford et al., 2002; Zvolensky et al., 2009). Yet, few studies have examined the prospective relationship between emotional responses to quitting and smoking cessation outcomes. Lastly, more recent research has identified novel predictors of quit attempt outcomes, including complementary and alternative reinforcers. Rooted in Behavioral Economic Theory (Green and Freed, 1993), increased engagement in substitute reinforcers, which are healthier alternative activities to smoking (e.g., physical activity), and decreased engagement in complementary reinforcers, which are activities that increase the reinforcing value of smoking (e.g., consuming alcohol), have been associated with greater probability of successful cessation. Results from a small lab study (Stoops et al., 2011) and a clinical trial of short-term abstinence (Goelz et al., 2014) indicate the need to examine the predictive significance of alternative reinforcers on long-term abstinence. Such analyses could help support the development and evaluation of novel behavioral interventions based on Behavioral Economic Theory to promote tobacco cessation. Thus, emerging from these studies is the picture that smokers attempting to quit may have a greater probability for success if they are able to better manage craving and withdrawal, negative emotional responses, and substitute and complementary reinforcers.

To date, however, few studies have prospectively examined long-term changes in these factors following treatment with transdermal nicotine as predictors of successful long-term cessation. Thus, this study, using data from a large clinical trial, examined changes in withdrawal and craving, emotional responses, and complementary and substitute reinforcers among successful abstainers 6 months after treatment initiation vs. those who returned to smoking.

## 2. Methods

### 2.1. Participants

Participants in this study completed an effectiveness clinical trial that evaluated 8, 24, and 52 weeks of transdermal nicotine (Schnoll et al., 2015; ClinicalTrials.gov Identifier: NCT01047527). For the current study, only participants randomized to 8 weeks of treatment were included in order to standardize nicotine patch treatment duration and to follow up on our prior study of predictors of short-term cessation (Goelz et al., 2014). To be eligible for the clinical trial, participants had to be 18 years of age or older, report smoking 10 cigarettes per day or more, and indicate an interest in quitting smoking. Exclusion criteria were limited to minimizing potential subject risk (see Schnoll et al., 2015) and, as a result, the present sample was relatively unique (e.g., included smokers with past or current psychiatric disorders).

### 2.2. Study procedures

Methods were approved by the University of Pennsylvania and Northwestern University Institutional Review Boards. Participants, recruited through advertisements, completed an in-person intake session to confirm eligibility. Eligible participants were randomized to 8, 24, or 52 weeks of transdermal nicotine and 12 behavioral counseling sessions. Participants received open-label 21 mg transdermal nicotine (Nicoderm CQ; GlaxoSmithKline, Research Triangle Park, NC) for 8 weeks and 8 behavioral counseling sessions. Counseling was brief, based on established treatment guidelines (Fiore et al., 2008), and focused on preparing for cessation, man-

aging urges and triggers to smoking, and developing strategies to avoid relapse. Data for this study were taken from assessments conducted at baseline (week-2), week 8, and 6 months. At 6 months, self-reported smoking cessation was confirmed using breath carbon monoxide (CO) assessed using the Vitalograph BreathCO monitor.

### 2.3. Measures

**2.3.1. Covariates.** At the baseline assessment, participants were asked to provide information about demographic (e.g., age, sex, race) and smoking-related (e.g., cigarettes per day, the Fagerström Test for Nicotine Dependence [FTND; Heatherton et al., 1991]) characteristics. In addition, as described previously (Kaufmann et al., 2015), saliva samples (5 ml) were collected at baseline to determine participant rate of nicotine metabolism based on the nicotine metabolite ratio (NMR).

**2.3.2. Withdrawal and craving.** The Minnesota Nicotine Withdrawal Scale (MNWS) measured withdrawal symptoms associated with quitting smoking (Hughes and Hatsukami, 1986). The MNWS assesses 7 American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) dimensions of nicotine withdrawal (i.e., anger, anxiety, depression, difficulty concentrating, increased appetite, insomnia, restlessness, impatience, and craving); a summary score was calculated. The 10-item brief Questionnaire of Smoking Urges (QSU; Cox et al., 2001) was used to assess craving for cigarettes; a total summary score was used.

**2.3.3. Inventory of Depressive Symptomatology.** The 30-item Inventory of Depressive Symptomatology (IDS; Rush et al., 1986, 1996) assessed the severity and frequency of depressive symptoms. The IDS includes symptoms of major depressive disorder as defined by the DSM-IV. Each item is scaled from 0 (not present) to 3 (very severe), yielding a total score. Depression severity can be classified as normal ( $\leq 15$ ), mild (16–24), moderate (25–32), moderate to severe (33–40) and severe ( $\geq 41$ ).

**2.3.4. Beck Anxiety Inventory.** We used the 21-item Beck Anxiety Inventory (BAI) to determine participant symptoms of anxiety (Beck et al., 1988). Each item was rated on a 4-point scale ranging from 0 to 3 and items were summed to obtain a total score. Total scores from 0 to 7 are considered to reflect a minimal level of anxiety; scores of 8–15 indicate mild anxiety; scores of 16–25 reflect moderate anxiety; and scores of 26–63 indicate severe anxiety.

**2.3.5. Pleasant Events Schedule.** The Pleasant Events Schedule (PES; MacPhillamy and Lewinsohn, 1982) is a self-report measure of the frequency and enjoyability of common rewarding activities and events engaged in by an individual over the past 30 days. We used the 45-item short-form version of the PES as in past studies (Audrain-McGovern et al., 2009, 2011). First, the cross product of the frequency score (0 = has not happened to 2 = happened often) and enjoyability score (0 = not pleasurable to 2 = very pleasurable) for each item provided a measure of an individual's reinforcement from that activity. Second, participants were asked whether they associated each activity with smoking or the urge to smoke; activities associated with smoking were defined as complementary reinforcers whereas activities not associated with smoking were defined as alternative reinforcers. The cross products of the substitute reinforcers were summed to provide an individual's overall index of substitute reinforcers and the cross products of the complementary reinforcers were summed to provide an individual's overall index of complementary reinforcers.

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