Behaviour Research and Therapy 78 (2016) 19–29

Contents lists available at ScienceDirect

Behaviour Research and Therapy

journal homepage: www.elsevier.com/locate/brat

A randomized clinical trial of a tailored behavioral smoking cessation preparation program

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ARTICLE INFO

Article history:
Received 1 September 2015
Received in revised form
24 November 2015
Accepted 30 November 2015
Available online 15 December 2015

Keywords:
Smoking cessation
Behavioral treatment
Randomized clinical trial

ABSTRACT

Despite considerable progress in reducing cigarette smoking prevalence and enhancing smoking cessation treatments, most smokers who attempt to quit relapse. The current randomized clinical trial evaluated the efficacy of an adjunctive behavioral smoking cessation treatment based on learning theory. Adult daily smokers were randomly assigned to standard treatment ($N = 47$) with nicotine patch and individual counseling or to standard treatment plus a "practice quitting" program involving seven sessions of escalating prescribed abstinence periods ($N = 46$) prior to a target stop smoking date. Practice quitting was designed to extinguish smoking in response to withdrawal symptoms. Retention in treatment was excellent and the treatment manipulation increased the interval between cigarettes across practice quitting sessions on average by 400%. The primary endpoint, seven-day point-prevalence abstinence four weeks post-quit, was not significantly affected by practice quitting (31.9% in the standard treatment condition, 37.0% in the practice quitting condition). Practice quitting increased latency to a first lapse among those who quit smoking for at least one day and prevented progression from a first lapse to relapse (smoking daily for a week) relative to standard treatment, however. Practice quitting is a promising adjunctive treatment in need of refinement to enhance adherence and efficacy.

1. Introduction

Smoking remains the leading preventable cause of death among adults in the U.S. [Centers for Disease Prevention and Control (CDC), 2008; U.S. Department of Health and Human Services, 2004]. Although more than half of current U.S. smokers attempt to quit each year, cessation failure and relapse remain the most likely outcomes of quit attempts (CDC, 2011). Currently available treatments, such as varenicline or combination nicotine replacement therapies offered with counseling, roughly triple success rates relative to placebo treatment, but still help fewer than 50% of smokers achieve abstinence lasting six-months or longer (Cahill, Stevens, Perera, & Lancaster, 2013; Fiore et al., 2008). Quitline counseling interventions with broad reach are also effective, but help fewer than 20% of smokers achieve lasting abstinence (Stead, Hartmann-Boyce, Perera, & Lancaster, 2013). As such, despite considerable progress, we still have an urgent need for novel smoking cessation interventions. Developing low-risk, low-cost adjunctive interventions that can supplement current first-line treatments may be a way to achieve the long-elusive goal of developing treatments that work for a majority of smokers. The aim of the current randomized clinical trial was to gather initial efficacy data on such an adjunctive smoking-cessation-preparation intervention based on contemporary learning theory.

Smoking is a learned behavior supported by both classical and operant conditioning (McCarthy, Baker, Minami, & Yeh, 2011). Many conditioned stimuli (e.g., lighters, ashtrays, internal states of distress or craving) elicit smoking motivation and serve as triggers for continued or renewed smoking (see Baker, Piper, McCarthy, Majeskie, & Fiore, 2004; McCarthy et al., 2011 for reviews). Internal signals of withdrawal may be particularly potent triggers of drug motivation and use (Baker et al., 2004). That is, avoidance and

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http://dx.doi.org/10.1016/j.brat.2015.11.015
0005-7967/

escape of withdrawal distress may be critical to the maintenance of smoking behavior (Baker et al., 2004). Self-reported withdrawal symptoms have been shown to emerge in just a few hours of abstinence (Hendricks, Ditre, Drobes, & Brandon, 2006). More subtle signs of withdrawal that may not enter awareness may nonetheless prompt smoking behavior (Baker et al., 2004). In support of this negative reinforcement model of smoking motivation, most returns to smoking begin within the first few weeks of a quit attempt (Brandon, Tiffany, Obremski, & Baker, 1990; Brown et al., 2008; Piasecki, Fiore, McCarthy, & Baker, 2002), when withdrawal is often most intense (Hughes, 2007; Shiffman, Patten, et al., 2006). A wealth of laboratory and clinical evidence supports the role of withdrawal in maintaining smoking behavior (Allen, Bade, Hatsukami, & Center, 2008; Welsch et al., 1999; West, Hajek, & Belcher, 1989; Zhou et al., 2009). Existing treatments may also work, in part, by reducing withdrawal and craving (McCarthy et al., 2008; Piper et al. 2008; Shiffman, Ferguson, Gwaltney, Balabanis, & Shadel, 2006) and thereby reducing smoking motivation.

If smoking is indeed maintained by avoidance or escape of withdrawal or similar affective states, then extinction of this avoidance behavior may be a promising adjunctive treatment approach, as others have suggested (Otto, Powers, & Fischmann, 2005; Otto, Safren, & Pollack, 2004). Extinction treatments are among the most effective psychotherapies developed to date and are the first-line treatments for many anxiety disorders (Barlow, Gorman, Shear, & Woods, 2000; Craske & Mystkowski, 2006; Foa et al., 2005; Mineka & Thomas, 1999; NICE, 2011). Recently, the concept of facilitating extinction through exposure to feared internal stimuli with prevention of drug use responding has been applied to treatment for substance use disorders. A pilot investigation of exposure to internal distress (elicited by hyperventilation) among individuals addicted to opiates indicated a medium-sized reduction in the percentage of positive drug screens in women (*Cohen's d* = 0.61), but not men (Pollack et al., 2002). By this same logic, an intervention that incrementally exposes smokers to withdrawal and associated symptoms may enhance a smokers' ability to endure withdrawal which may, in turn, increase the likelihood of maintaining abstinence after quitting. Evidence supporting the utility of such an approach is beginning to accumulate. A series of single-subject designs has supported the utility of combining graded interoceptive exposure to withdrawal induced by smoking deprivation and exposure to interoceptive cues of anxiety in smokers high in anxiety (Feldner, Smith, Monson, & Zvolensky, 2013; Zvolensky, Yartz, Gregor, Gonzalez, & Bernstein, 2008). An open trial of a treatment targeting anxiety sensitivity in Argentinian smokers has also generated promising evidence that interventions involving graded exposure to withdrawal prior to quitting may facilitate successful quitting (Zvolensky, Bogiaizian, Lopez Salazar, Farris, & Bakhshaie, 2011). Thus, there is emerging evidence that exposure to interoceptive cues associated with substance use may facilitate extinction of substance use.

Extinction is complicated and fragile, however, as demonstrated by extensive animal and human research (see Vervliet, Craske, & Hermans, 2013 for a review). Although the exact nature of the learning during extinction that leads to observable changes in behavior is not yet clear, it seems as though new, inhibitory learning is critical (Bouton, 2004; Vervliet et al., 2013). Extinction is highly stimulus- and context-dependent (Vervliet et al., 2013). For this reason, it is important to conduct extinction training in the contexts (including internal states) in which a return of smoking is most likely to occur, in the presence of the conditioned stimuli most likely to elicit smoking responses (Otto, O'Cleirigh, & Pollack, 2007; Vervliet et al., 2013). The laboratory and the clinic are therefore not the optimal contexts for this form of treatment. *In vivo* extinction in smokers' real-world settings is more likely to facilitate robust behavior change, in addition to being less burdensome and more feasible as an adjuvant treatment. For this reason, the current randomized trial involves extinction of smoking behavior in the presence of withdrawal (induced by prescribed abstinence) in smokers' natural environments on different days of the week. In this way, the current study is similar to an independent pilot study ($N = 16$) of a multicomponent treatment that included four sessions of exposure to withdrawal and smoking cues (e.g., lighters, ashtrays) during escalating periods of abstinence of one to four hours (Brown et al., 2008). The current study differs from this earlier uncontrolled pilot study, however, in isolating the additive benefit of practice quitting as an adjunct to standard nicotine patch and brief counseling treatment, increasing the dose of exposure to seven sessions, and tailoring the duration of prescribed abstinence based on smokers' past success.

The current study evaluates the additive benefit of a behavioral intervention designed to systematically expose smokers to periods of abstinence and withdrawal prior to a target quit day. The aim of the treatment was to prepare smokers to quit by weakening or inhibiting associations between smoking and diverse internal and external real-world, personally relevant stimuli and contexts. Smokers were randomized to receive either standard treatment (nicotine patch and smoking cessation counseling) alone or standard treatment plus 'practice quitting.' Periods of abstinence were tailored to the individual based on their previous longest period between cigarettes to optimize progress and gradually increase exposure to withdrawal. Rest days were offered between practice-quitting sessions in an effort to enhance the acceptability of the treatment and also to enhance the retrieval strength of new extinction learning (Vervliet et al., 2013). Practice quitting was scheduled to take place from overnight into the next morning, to optimize exposure to interoceptive withdrawal cues likely to be strongest after overnight abstinence (when blood nicotine levels typically fall). The seven practice quits occurred once on every day of the week in an effort to extend the contexts in which abstinence, and associated exposure to withdrawal symptoms, occurred.

We assessed the feasibility and acceptability of the practice quitting intervention by examining attrition and abstinence adherence rates. The primary outcome of interest was seven-day point-prevalence abstinence four weeks after the quit attempt. We hypothesized that practice quitting would enhance cessation success compared to the standard treatment control. Building on evidence that past duration of abstinence from tobacco predicts future success at quit attempts (e.g., Hyland et al., 2006; Vangeli, Stapleton, Smit, Borland, & West, 2011), we also expected that longer successful practice quitting intervals prior to the quit day would predict improved cessation outcomes. We examined whether practice quitting enhanced success above and beyond standard treatment across cessation milestones (Shiffman, Scharf, et al., 2006), predicting greater initial cessation success and longer time to lapse or relapse after quitting among those in the practice quitting condition.

2. Method

2.1. Participants

Participants were adult, daily smokers from central New Jersey recruited through direct mail and flyers. Inclusion criteria for this study required participants be over age 18, English-literate, motivated to quit smoking (at least 6 on a 10-point scale), and smoking at least 10 cigarettes per day for at least 6 months with at least 8 parts per million carbon monoxide (CO) in their expired breath at baseline. Study exclusion criteria included: contraindications to nicotine patch use (heart attack or heart surgery in the past three