



Full length article

Toward precision smoking cessation treatment II: Proximal effects of smoking cessation intervention components on putative mechanisms of action



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ABSTRACT

Background: Understanding how smoking cessation treatments exert their effects can inform treatment development and use. Factorial designs allow researchers to examine whether multiple intervention components affect hypothesized change mechanisms, and whether the affected mechanisms are related to cessation.

Methods: This is a secondary data analysis of smokers recruited during primary care visits (N=637, 55% women, 87% white) who were motivated to quit. Participants in this fractional factorial experiment were randomized to one level of each of six intervention factors: Prequit Nicotine Patch vs None, Prequit Nicotine Gum vs None, Preparation Counseling vs None, Intensive In-Person Counseling vs Minimal, Intensive Phone Counseling vs Minimal, and 16 vs 8 Weeks of Combination Nicotine Replacement (nicotine patch + nicotine gum). Data on putative mechanisms (e.g., medication use, withdrawal, self-efficacy) and smoking status were gathered using daily assessments and during follow-up assessment calls.

Results: Some intervention components influenced hypothesized mechanisms. Prequit Gum and Patch each reduced prequit smoking and enhanced prequit coping and self-efficacy. In-Person Counseling increased prequit motivation to quit, postquit self-efficacy, and postquit perceived intratreatment support. Withdrawal reduction and reduced prequit smoking produced the strongest effects on cessation. The significant effect of combining Prequit Gum and In-Person Counseling on 26-week abstinence was mediated by increased prequit self-efficacy.

Conclusions: This factorial experiment identified which putative treatment mechanisms were influenced by discrete intervention components and which mechanisms influenced cessation. Such information supports the combined use of prequit nicotine gum and intensive in-person counseling as cessation interventions that operate via increased prequit self-efficacy.

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1. Introduction

In the United States, cigarette smoking kills almost half a million people each year, making it the leading preventable cause of death and disease (U.S. Department of Health and Human Services, 2014). While evidence-based treatments can more than double a smoker's chances of quitting (Fiore et al., 2008; West et al., 2015), we know relatively little about how these treatments work. A clearer under-

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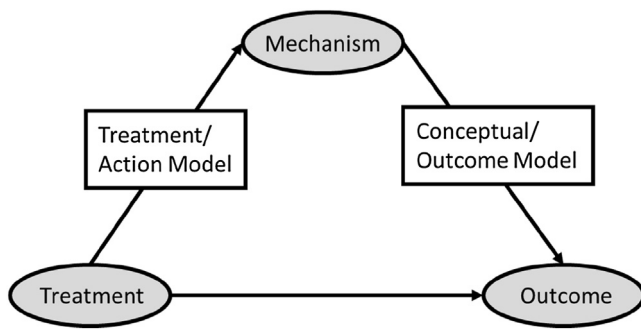


Fig. 1. The mediation model.

standing of how treatments work should enhance both treatment development and use.

Mediation analyses have been used to identify mechanisms involved in both pharmacotherapy and counseling effects. Pharmacotherapies appear to enhance long-term abstinence primarily by suppressing withdrawal symptoms, especially craving (e.g., Bolt et al., 2012; Ferguson et al., 2006; Lerman et al., 2002), but other mechanisms may also be implicated (McCarthy et al., 2008; Piper et al., 2008). Research on counseling treatment has fairly consistently supported self-efficacy as a mediator of counseling effects (Graham et al., 2015; Hendricks et al., 2010; McCarthy et al., 2010; Schuck et al., 2014). However, only isolated findings support the roles of other putative mediators: decreased expectations of smoking reward (Schuck et al., 2014), greater avoidance of smoking cues (McCarthy et al., 2010, 2008; Schuck et al., 2014), increased perceived partner support (Graham et al., 2015), and reduced guilt and demoralization following repeated lapses (McCarthy et al., 2010). This inconsistency may be due to variation in counseling interventions in these studies (e.g., lengths and types of treatment, control conditions, routes of counseling delivery).

The slow progress in this research area may be due, in part, to the use of randomized controlled trial (RCT) designs. Such designs typically compare an “active” treatment comprising multiple intervention components (e.g., pharmacotherapy, a website, and counseling) with a control condition comprising a smaller subset of components (e.g., pharmacotherapy and a website). This approach has limitations. First, if the active treatment differs from the control treatment (on either the outcome or on a putative mechanism), it is unclear if the effect is due to the main effect of the added component(s) itself, or instead due to the component’s interactions with any of the other components. This is a concern since interactions amongst intervention components may be common (Baker et al., 2016). Further, RCTs reveal the effect of a component as it is used with a specific combination of other components; such designs do not reveal whether the observed effects would occur when used with various mixes of other adjuvants. Conversely, factorial designs allow researchers to efficiently explore the mechanisms of multiple, relatively discrete, intervention components. They also permit evaluation of both main and interaction effects, revealing whether mediation differs as function of adjuvant treatment.

Mediation analyses address two key questions regarding how treatments work (Kenny et al., 1998; MacKinnon et al., 2002; McCarthy et al., 2007). First, the *treatment or action model* focuses on whether the treatment affects a mechanism that is hypothesized to produce the desired clinical or public health outcome (see Fig. 1). Second, the *conceptual or outcome model* focuses on whether the proposed mechanisms actually influence the desired clinical outcome (e.g., abstinence). Evaluating both models may be informative whether or not significant treatment effects are found (McCarthy et al., 2007). For instance, a failure of the treatment model suggests

that the treatment was inadequate; it failed to activate its targeted mechanisms. A failure of the outcome model suggests that the model of change was inadequate; the treatment may have affected the targeted mechanisms, but these did not influence the clinically significant outcomes. The former suggests a need to strengthen the treatment, the latter suggests a need to target different mechanisms.

The analyses reported in the current paper were obtained in a factorial experiment that yielded no significant main effects on abstinence; however, three 2-way interactions were found (Piper et al., 2016). This paper therefore, examined potential mediators for these interaction effects. It also examined the treatment and outcome models for the nonsignificant main effects since it is important to determine if an intervention activates targeted mechanisms and whether the targeted mechanisms influence abstinence (Piper et al., 2016).

The intervention components in this factorial experiment were selected based on evidence that they would be effective for the phase of the smoking treatment in which they were to be used (Baker et al., 2011; Collins et al., 2016; Piper et al., 2016). Three Preparation-phase interventions were designed to prepare smokers for quitting: 3 weeks of prequit nicotine gum (Prequit Gum), 3 weeks of prequit nicotine patch (Prequit Patch), and prequit counseling (Preparation Counseling: 3 sessions designed to help smokers make 2 practice quit attempts, reduce their smoking, and develop coping skills prior to quitting). Prequit Patch and Prequit Gum were intended to: 1) reduce smoking prior to quitting (Hawk et al., 2015; Stead and Lancaster, 2007), 2) increase postquit medication adherence, and 3) reduce withdrawal prequit and postquit. Preparation Counseling was hypothesized to: 1) increase the use of coping skills (Fiore et al., 2008; Shiffman, 1984); 2) increase cessation motivation and self-efficacy (Williams et al., 2006a,b); 3) increase intratreatment social support (Fiore et al., 2008); 4) reduce tobacco dependence via decreased smoking for 2 weeks prior to quitting (Cinciripini et al., 1997; Hughes and Carpenter, 2006); and 5) reduce exposure to smoking cues through altering life contexts and behaviors (Abrams et al., 1988; Juliano and Brandon, 1998). The two Cessation-phase interventions were designed to help smokers cope with challenges typically encountered early in the postquit period: e.g., negative affect, craving (Baker et al., 2004a,b; McCarthy et al., 2006) and lapses (Kenford et al., 1994). The Cessation-phase In-Person and Phone Counseling both comprised treatment elements identified as effective by the 2008 PHS Guideline: skill training designed to increase avoidance of smoking triggers and execution of coping responses, and intra-treatment support designed to increase perceived intra-treatment social support (Fiore et al., 2008).

In sum, this research used a factorial experiment to determine whether: 1) distinct, individual Preparation and Cessation-phase intervention components produced hypothesized proximal effects (treatment model); 2) the hypothesized proximal effects influenced long-term abstinence (outcome model); and 3) the significant effects of specific combinations of intervention components on long-term abstinence were mediated by hypothesized proximal effects.

2. Methods

2.1. Procedure

This is a secondary data analysis of a fractional factorial screening experiment that assessed the efficacies of six smoking cessation intervention components (Piper et al., 2016). Participants (N = 637; 55% women, 87% white) were recruited from primary care clinics during regular visits. Eligible patients (≥ 18 years old; ≥ 5

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