



A randomized controlled trial of a smoking cessation self-help intervention for dual users of tobacco cigarettes and E-cigarettes: Intervention development and research design[☆]

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ABSTRACT

Electronic Nicotine Delivery Systems, also called electronic cigarettes or e-cigarettes, have been available for over a decade and use has been increasing dramatically. The primary reported reasons for use are to aid smoking cessation or reduction, yet a significant proportion appear to be long-term users of both products (“dual users”). Dual users may be motivated to quit smoking and might benefit from a behavioral intervention for smoking cessation. This paper describes the intervention development, as well as the design, methods, and data analysis plans for an ongoing randomized controlled trial (RCT). Formative research and learner verification were conducted to create a usable, understandable, and acceptable self-help intervention targeting dual users. The efficacy is being tested in an RCT with current dual users ($N = 2900$) recruited nationally and randomized to one of three conditions. The Assessment Only (ASSESS) group only completes assessments. The Generic Self-Help (GENERIC) group receives non-targeted smoking cessation booklets and supplemental materials sent monthly over 18 months. The e-cigarette Targeted Self-Help (eTARGET) group receives the newly developed intervention (targeted booklets and supplemental materials) sent over the same period. All participants complete self-report surveys every 3 months over 2 years. The primary study outcome is self-reported 7-day point prevalence abstinence. Cost-effectiveness metrics for the GENERIC and eTARGET interventions will also be calculated.

1. Introduction

Research on electronic nicotine delivery systems, also called electronic cigarettes or e-cigarettes (ECIGs), is still in the nascent stage with open questions about their health consequences, addiction liability, and smoking cessation potential [1,2]. To date, there have been few longitudinal studies [3,4] and the behavior of ECIG users over time remains unclear. ECIGs cannot be overtly marketed as pharmacotherapy for treating tobacco dependence, yet survey research indicates that the primary motivations for their use are to aid smoking cessation or

smoking reduction [5–7]. Evidence regarding the smoking cessation benefits of ECIGs is inconclusive; [8] one hypothesis is that they function similar to traditional forms of nicotine replacement therapy (NRT). The efficacy of NRT is greatly improved when combined with minimal behavioral interventions. Although millions of smokers are simultaneously using ECIGs [9,10], for the purpose of quitting smoking, they usually do so without receiving any behavioral assistance. In addition, although more likely to make a quit attempt than smokers alone, they are not significantly more likely to actually quit [11]. Thus, an opportunity exists to facilitate smoking cessation among the large population

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of “dual users” who have demonstrated initial action toward smoking cessation by initiating ECIGs and are primed to benefit from a minimal intervention to enhance their chances of tobacco abstinence.

To capitalize upon this circumstance, we adapted our cost-effective, previously validated self-help smoking cessation intervention, *Forever Free®: Stop Smoking for Good* [12], for dual users. That self-help intervention was developed to assist smokers with cessation, and it demonstrated efficacy in a recent randomized controlled trial (RCT) [12]. It was designed to capture key content from empirically supported cognitive-behavioral interventions [13] and to provide it over an extended period of time.

The present study applies this efficacious intervention approach (extended self-help) to the rapidly changing landscape of tobacco use marked by dramatic increases in the dual use of ECIGs and conventional, combustible cigarettes. Reported rates of dual use range from approximately 10% to 35% among current cigarette smokers [14–16]. On the one hand, there is cause for public concern because chronic dual use maintains the multiple health risks associated with smoking while potentially adding yet unknown risks of ECIGs. On the other hand, dual use may offer an opportunity to transform dual users' ECIG use from maintaining tobacco smoking to promoting smoking cessation, with the ultimate goal of complete nicotine cessation, given other potential risks [17–20].

This paper describes the intervention adaptation for dual users, as well as the design, methods, and data analysis plans for the ongoing RCT. The primary aim is to develop and test a minimal self-help smoking-cessation intervention for current dual-users of tobacco cigarettes and ECIGs. Given that small improvements in cessation may not be justified if they require substantially greater cost, we will also compare the interventions on cost-effectiveness (cost per incremental cessation and expected life-years gained). A secondary surveillance aim will assess the dynamic process of tobacco smoking and ECIG use longitudinally, to capture the natural progression of dual use.

2. Methods

2.1. Study I: Intervention development

The intervention developed in this study is based on the original *Forever Free®* booklets [21,22], initially designed to prevent smoking relapse. Brandon and colleagues later modified the *Forever Free®* booklets to include instruction on smoking cessation, creating a new version titled, *Forever Free®: Stop Smoking for Good* [12]. The first booklet in the series provides a general overview about quitting smoking, and each of the remaining nine booklets includes more extensive information on a topic related to maintaining abstinence: *Smoking Urges*; *Smoking and Weight*; *What if You Have a Cigarette?*; *Your Health*; *Smoking, Stress, and Mood*; *Lifestyle Balance*; *Life without Cigarettes*; *The Benefits of Quitting Smoking*; and *The Road Ahead*. The content of these booklets was based on cognitive-behavioral theory [23,24] and empirical evidence regarding the nature of tobacco dependence, cessation, and relapse [25]. They were designed originally as a means of translating the cognitive-behavioral counseling that occurs in a smoking cessation clinic into a written format that would be more accessible to a larger population of smokers. In addition, perceived social support appears to benefit smoking cessation [26,27]. Thus, new motivational pamphlets were added to the intervention to provide a social support analog via tri-fold color pamphlets (*How I Quit Smoking*) that reinforce key messages about quitting smoking (e.g., dealing with stress, keeping weight gain in perspective, finding other forms of positive reinforcement). To further induce a sense of social support, the message is communicated via a first-person narrative from a former smoker, incorporating photographs of the purported smoker.

A systematic approach was used to adapt and refine the *Stop Smoking for Good* booklets and the *How I Quit Smoking* motivational pamphlets for dual users [28]. First, in-depth interviews ($N = 28$) were

conducted to identify and explore new content topics for inclusion that would be relevant for dual users. Two trained doctoral level interviewers conducted all in-depth interviews with participants. Each interview lasted approximately 60 min and participants were provided \$30 compensation. Participants represented four subgroups: (1) current dual users without interest in quitting smoking; (2) current dual users who had attempted, unsuccessfully, to quit smoking; (3) current ECIG users who had successfully quit smoking; and (4) former dual users who had quit both products. These subgroups were selected to obtain a wide range of smoking and e-cigarette experiences and perspectives from individuals across the continuum of dual use, from those unmotivated to quit smoking to those who were successful in quitting both products. The participant sample was 48% female, 79% Caucasian, with 15% identifying as Hispanic. The average age was 48.8 ($SD = 14.2$), and 48% reported annual household income above \$50,000. Current and former smokers smoked a median of 16–20 cigarettes per day and vaped a median of 15–19 times a day.

Verbatim transcripts were coded using an inductive content analysis and the constant comparative method [29]. The constant comparative method is a process in which newly collected data are compared to previous data. The process is used to extrapolate and identify emergent themes related to the study aims, and enables coders to identify when and if saturation has occurred.

Based on these findings, as well as existing and emerging research and theory regarding both ECIGs and the use of NRT for smoking cessation, deeper content (i.e., specific advice for quitting smoking for dual users) modifications regarding quitting smoking using ECIGs were incorporated. Examples include: gradually reducing nicotine levels; switching from a tobacco flavor to an alternative flavor; and limiting ECIG use to places one would normally use tobacco cigarettes (i.e., not expanding use). In addition, language that reflects the current preferences of the target population was used throughout the materials. For example, ECIG use is referred to as “vaping” and the ECIGs themselves are often called “personal vaporizers.”

The existing tri-fold color pamphlets (*How I Quit Smoking*) were also revised to enhance relevance for dual users. To attain a high level of face validity, the pamphlets will include language, photos, and graphics that incorporate ECIGs. Additionally, the illustrative vignettes in the booklets and the personal stories in the pamphlets were replaced or modified based on testimonials from the interviews. For example, one of the pamphlets was modified to describe a smoker's experience using tobacco-flavoring early on to ease the transition to ECIGs, and then switching to other flavors to reduce the association with smoking. During the interviews, we also gathered feedback about the existing *Stop Smoking for Good* booklets in terms of tone and other important elements of smoking cessation message design for this audience. Participants responded favorably to the booklets and provided suggestions on how to best incorporate information about quitting smoking using ECIGs. For example, participants felt that ECIGs should be presented separately from traditional forms of nicotine replacement therapy (NRT) as a quit aid. In addition, participants indicated mixed opinions regarding the value of ECIGs for coping with stress. Therefore, new content sought to clarify and reinforce the use of an ECIG over a traditional cigarette during times of stress. Furthermore, because the long-term health consequences of ECIG use remain unknown, we elected to include progressively stronger and more specific advice to discontinue ECIG use following smoking cessation. However, because during the interviews the majority of participants felt it would be off-putting to include these messages early on in the series, we introduced these messages in the latter half of the booklet series. Finally, two initial brochures, one for each intervention condition, were developed to provide participants with an introduction to the *If You Vape* booklets and the *Stop Smoking for Good* booklets, respectively, and the goal of using ECIGs to quit smoking.

Next, learner verification interviews ($N = 20$ dual users) were conducted to assess the suitability of the revisions. This methodology

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