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Smoking relapse-prevention intervention for cancer patients: Study design and baseline data from the surviving SmokeFree randomized controlled trial☆

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ABSTRACT

Continued smoking after a cancer diagnosis contributes to several negative health outcomes. Although many cancer patients attempt to quit smoking, high smoking relapse rates have been observed. This highlights the need for a targeted, evidence-based smoking-relapse prevention intervention. The design, method, and baseline characteristics of a randomized controlled trial assessing the efficacy of a self-help smoking-relapse prevention intervention are presented. Cancer patients who had recently quit smoking were randomized to one of two conditions. The Usual Care (UC) group received the institution's standard of care. The smoking relapse-prevention intervention (SRP) group received standard of care, plus 8 relapse-prevention booklets mailed over a 3 month period, and a targeted educational DVD developed specifically for cancer patients. Four hundred and fourteen participants were enrolled and completed a baseline survey. Primary outcomes will be self-reported smoking status at 6 and 12-months after baseline. Biochemical verification of smoking status was completed for a subsample. If found to be efficacious, this low-cost intervention could be easily disseminated with significant potential for reducing the risk of negative cancer outcomes associated with continued smoking.

1. Introduction

The potential negative implications of continued smoking in cancer patients are well established. Persistent smoking after a cancer diagnosis places the individual at increased risk for a secondary malignancy, poor cancer treatment outcomes, and decreased quality of life [1–3]. In fact, the 2014 Surgeon General's report concluded that sufficient evidence exists to demonstrate a causal link between continued smoking and poor cancer outcomes for patients and survivors [4].

Fortunately, cancer patients are highly motivated to quit smoking [5]. In a previous study, 84% of patients reported making at least one quit attempt and 69%, reported making multiple quit attempts [6]. The majority of quit attempts occur at the time of diagnosis [5,7]. Although many cancer patients attempt to quit, studies have reported smoking relapse rates among cancer patients ranging from 13% to 60% [8–13], with abstinence rates in half of these studies validated biochemically. Importantly, even low relapse rates are cause for concern due to the considerable negative health impact and quality of life consequences. Therefore, interventions are needed to prevent smoking relapse among cancer patients who have already achieved initial smoking cessation.

Brandon and colleagues [14,15] previously tested a self-help smoking relapse-prevention intervention for the general population (titled *Forever Free*®) and found that it was efficacious and cost-effective. This study extends the self-help relapse-prevention approach to a cancer patient population. Indeed, several smoking relapse risk factors, such as nicotine dependence, negative affect, and low self-efficacy, have been observed in both general and oncology populations [16–20]. Previous research has suggested that there is also a range of unique factors associated with relapse among this population that must be considered: pain and fatigue, delayed relapse rates, cancer-specific risks of continued smoking, and cancer-relevant benefits of quitting smoking [5,21–23].

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Therefore, we developed an educational DVD, titled Surviving SmokeFree®, to target the unique needs of cancer patients. The Forever Free® booklets and Surviving SmokeFree® DVD address both the common and cancer-specific relapse risk factors, respectively. This multimodal intervention also represents a potentially cost-effective and highly disseminable smoking relapse-prevention intervention for cancer patients.

This paper describes the design, methods, and data analysis plan for a randomized controlled trial (RCT). Baseline characteristics of the sample are also presented to highlight the feasibility of recruiting patients who have diverse cancer sites and stages. The primary aim of the RCT is to test the efficacy of a multimodal empirically-based, targeted smoking relapse prevention intervention for cancer patients. Secondary aims will explore the influence of potential moderators on intervention outcomes and examine the degree to which the intervention impacts outcomes via theoretically-derived mediating variables.

2. Methods

2.1. Participants

Participants included recently diagnosed cancer patients receiving the first round of treatment at Moffitt Cancer Center, a NCI-designated Comprehensive Cancer Center in Tampa, Florida. At the time of enrollment, eligible patients were at least 18 years of age, able to speak and read English, had smoked at least 10 cigarettes per day (CPD) for at least one year prior to their cancer diagnosis, and had quit smoking within the past 90 days. A quit was defined as self-reported smoking abstinence for at least 24 h. Previous research suggests that the risk of smoking relapse is highest among those who have recently quit [24], thus our range was from 24 h to 90 days quit, after which the risk of smoking relapse is reduced. Patients diagnosed with distant metastases (malignancies that have spread from the original tumor to distant organs or lymph nodes), were excluded to avoid added patient burden. Patients were recruited by trained research staff from inpatient units and various outpatient clinics. The study was approved by the University of South Florida's institutional review board.

2.2. Study design

The initial phase of the study was dedicated to the development of the targeted supplementary educational DVD, titled Surviving SmokeFree®. Development of the DVD was guided by our formative work [23], as well as relevant research and theory on smoking relapse-prevention. Our intervention was informed by Witkiewitz and Marlatt's (2004) [25] reconceptualized cognitive-behavioral model of relapse, which posits that relapse risk is a dynamic interaction of distal and proximal risks. This framework includes the interaction of background factors (family history, dependence), physiological states (e.g., withdrawal, pain, fatigue), affective states, cognitive processes (e.g. motivation) and coping skills in influencing relapse. The randomized trial consisted of two arms, Usual Care (UC) and Smoking Relapse Prevention (SRP). The UC group received standard of care (i.e. a brief clinical smoking intervention provided by the institution's Tobacco Treatment Specialist). Participants randomized to the SRP group received standard of care, viewed the Surviving SmokeFree® DVD, and received the first booklet of the *Forever Free*® series, along with a copy of Surviving SmokeFree® DVD. The remaining 7 booklets were mailed over a three month period. The primary outcome is smoking relapse as measured by self-reported 7-day point prevalence. We hypothesized that participants in the SRP group will demonstrate lower rates of smoking relapse at 6 and 12 months. Fig. 1 summarizes the intervention and assessment distribution time points.

2.3. Intervention conditions

2.3.1. Usual Care (UC)

Participants randomized to the UC group received the institution's standard of care, which included a one-time routine assessment of smoking behavior and a brief clinical intervention (5–15 min) with the tobacco treatment specialist. Specifically, patients received brief counseling based on the 5 As Clinical Practice Guidelines; Ask about tobacco use, Advise to quit, Assess willingness to make a quit attempt, Assist in quit attempt, Arrange for follow-up [17]. Depending on patient interest, patients were also offered information about local and state smoking resources (e.g., Quitline), educational brochures, and assistance with obtaining pharmacotherapy (i.e., varenicline, bupropion, or nicotine replacement therapy).

2.3.2. Smoking relapse-prevention intervention (SRP)

Study participants randomized to the SRP group received standard care as described above, including the brief clinical intervention from the tobacco treatment specialist, as well as our newly developed smoking-relapse prevention intervention comprising the series of 8 Forever Free® booklets and the Surviving SmokeFree® *DVD.* Intervention components are described below.

2.3.2.1. Forever Free® booklets. The first booklet in the series, received at study enrollment, presented a summary of the basic relapse-prevention principles and techniques. This booklet included topics such as nicotine dependence, situations that place the person at high risk for relapse, coping with urges to smoke, making lifestyle changes, and ways to handle an initial "slip" [14]. The seven remaining booklets, mailed during the 3 subsequent months post-recruitment, provided more in-depth

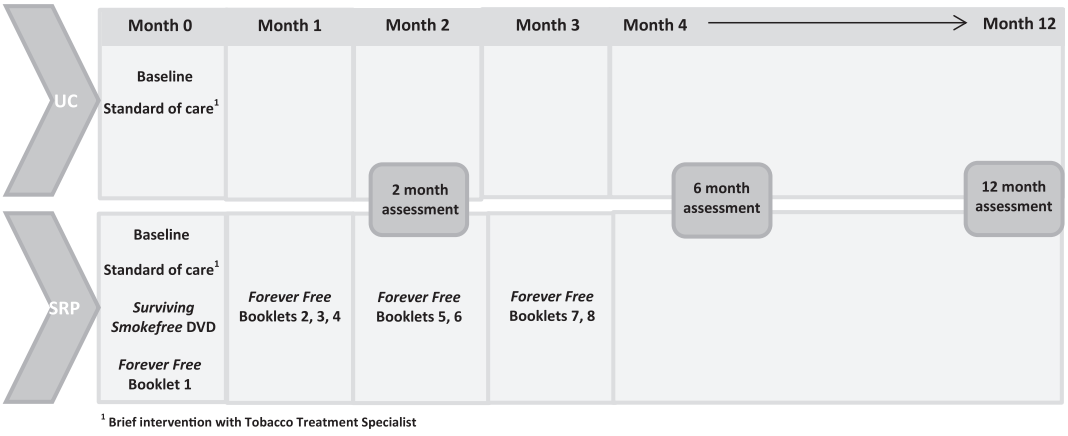

Fig. 1. Intervention and assessment distribution schedule.