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Implementation, recruitment and baseline characteristics: A randomized trial of combined treatments for smoking cessation and weight control

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ABSTRACT

Background: Two-thirds of treatment-seeking smokers are obese or overweight. Most smokers are concerned about gaining weight after quitting. The average smoker experiences modest post-quit weight gain which discourages many smokers from quitting. Although evidence suggests that combined interventions to help smokers quit smoking and prevent weight gain can be helpful, studies have not been replicated in real world settings.
Methods: This paper describes recruitment and participant characteristics of the Best Quit Study, a 3-arm randomized controlled trial testing tobacco cessation treatment alone or combined with simultaneous or sequential weight management. Study participants were recruited via tobacco quitlines from August 5, 2013 to December 15, 2014.
Results: Statistical analysis on baseline data was conducted in 2015/2016. Among 5082 potentially eligible callers to a tobacco quitline, 2540 were randomized (50% of eligible). Compared with individuals eligible but not randomized, those randomized were significantly more likely to be female (65.7% vs 54.5%, $p < 0.01$), overweight or obese (76.3% vs 62.5%, $p < 0.01$), more confident in quitting ($p < 0.01$), more addicted (first cigarette within 5 min: 50.0% vs 44.4%, $p < 0.01$), and have a chronic disease (28.6% vs. 24.4%, $p < 0.01$). Randomized groups were not statistically significantly different on demographics, tobacco or weight variables. Two-thirds of participants were female and white with a mean age of 43.
Conclusions: Adding weight management interventions to tobacco cessation quitlines was feasible and acceptable to smokers. If successful for cessation and weight outcomes, a combined intervention may provide a treatment approach for addressing weight gain with smoking cessation through tobacco quitlines.
Trial registration: Clinicaltrials.gov NCT01867983.

1. Introduction

Tobacco use continues to incur high costs to individuals, families and many nations [1]. In 2014, 16.8% of U.S. adults (95% CI = 16.1–17.4) reported they were currently smoking and a majority expressed a desire to quit and have made at least one quit attempt [2]. Smoking cessation counseling and FDA approved medications help individuals quit tobacco but relapse is high [3]. Quit rates using point prevalence intent-to-treat abstinence for telephone based cessation treatments vary greatly depending on treatment intensity, survey response rates and demographic characteristics of callers. For example, published quit rates range from 14 to 50% at 6 months and 17–23% at 12 months [4–10]. Notably, the likelihood of gaining weight is cited as a common barrier to successful quitting [11–14]. Research indicates that approximately 75% of smokers gain weight after quitting and that the weight gain is usually modest (5–6 kg) [15–19]. However, it is

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estimated that 10–15% of smokers who are trying to quit gain more than 10 kg and the weight gain can be permanent without lifestyle adjustments [20]. Efforts to curb excessive weight gain while maintaining a successful quit have led to the development and testing of smoking cessation interventions that also address weight gain [16,17,21–23]. Systematic reviews of such combined treatments have shown that some interventions that added weight control content to cessation treatment limited quit related weight gain, at least for the short-term, without harming smoking abstinence [16,17,21,22,24]. However, the latest Cochrane review concluded that evidence was insufficient to make strong recommendations for adding weight based interventions to tobacco cessation treatment [16]. Given this uncertainty, more research is needed. One successful study by Spring and colleagues compared tobacco cessation treatment alone versus the simultaneous or sequential addition of a weight management intervention [25]. Results showed that a sequential treatment approach (weight management treatment after the quit date), reduced weight gain to a greater extent than simultaneous treatment or cessation treatment alone [25]. Surprisingly, both combined treatments showed a non-significant trend for better cessation rates than smoking cessation only. This trial was intensive, in-person, group-based and involved only women smokers, like most other prior intervention trials testing combined smoking and weight interventions. The Best Quit study (BQS), described in an earlier protocol paper [26], aims to replicate and extend this prior efficacy trial in the context of an effectiveness study [25]. To our knowledge no studies have tested combined tobacco and weight control interventions in a population based setting. The study protocol and interventions from the prior trial were adapted for telephone delivery and delivered via national tobacco cessation quitlines. Quitlines are an ideal setting for testing and disseminating successful interventions in part because, like the general population, over two thirds of state quitline callers are overweight or obese and two thirds have significant concerns about gaining weight after quitting tobacco [8].

This paper describes the acceptability of adding weight based content to state and commercial quitlines by describing recruitment challenges and enrolled participants.

2. Study objectives and results

This paper addresses the following questions: Will smokers seeking help via quitlines want help limiting weight gain? Will smokers accept the invitation to participate in the randomized trial? Are baseline characteristics similar across the three groups?

3. Materials and methods

The Best Quit Study (BQS) is a 3-arm randomized controlled trial in which eligible and consenting smokers who called a state or employer-sponsored quitline were randomly assigned to tobacco cessation treatment alone, to the simultaneous delivery of tobacco and weight management treatment, or to tobacco cessation treatment followed by weight management intervention. The study was approved by the Western Institutional Review Board and is described in detail in a prior paper [26].

3.1. Setting

This translational, effectiveness study was conducted at Alere Wellbeing (a solely owned subsidiary of Optum) which is the largest provider of tobacco cessation quitlines in the US, serving 27 States and 750 employer groups and health plans. We conducted the study in ten quitlines from nationally distributed employer groups (commercial quitlines) and three state quitlines (Indiana, Maryland, North Carolina).

3.2. Population

Participants who called into the quitline between August 5, 2013 and December 15, 2014 were eligible for the study if they were age 18 and older, smoked at least 10 cigarettes per day, stated that they were ready to quit in the next 30 days, requested counseling, and were able to speak and read English. Additional screening criteria were access to a phone and internet and willingness to receive 10 phone calls from the quitline. Exclusion criteria included pregnancy, a BMI below 18.5, prior or planned weight loss surgery, currently enrolled in a weight loss program, and having diabetes or a current eating disorder. The latter variable was assessed with one question: 'Have you ever been told by a healthcare provider or mental health professional that you have an eating disorder such as anorexia or bulimia?' We excluded underweight individuals (BMI $<$ 18.5) because the weight management intervention was not designed for this population.

3.3. Recruitment and randomization

Quitline callers who met eligibility criteria and gave informed consent to participate were randomly assigned in blocks of 10 without stratification by a computer generated algorithm to one of three groups of equal proportions: 1) tobacco cessation treatment, 2) simultaneous tobacco plus weight management treatment or 3) tobacco cessation followed by weight management (sequential treatment). All groups received 10 counseling calls. The first call was initiated by the tobacco user; the remaining calls were initiated by a coach. Participants were encouraged to call the quitline between proactive calls or after completing treatment if they wanted extra support. Because the standard tobacco cessation quitline offers 5 counseling calls and adding 5 weight management calls to the sequential group resulted in 10 calls, we created attention-matched conditions by adding 5 nonspecific healthy living calls to both the standard quitline protocol (contact control condition) and to the simultaneous treatment condition. In this way we were able to equalize the number of counseling sessions across the three groups (Fig. 1). To maximize participation rates in each call, coaches made 5 attempts to reach participants. Those not reached were sent reminder letters in the mail and an email stating 'your coach is trying to reach you'.

3.4. Interventions

A comprehensive description of the interventions, counselor training and key intervention strategies are presented in a prior paper [26] and briefly summarized here. Alere Wellbeing Programs (Cessation treatment and Weight Management) are based on Social Cognitive Theory (SCT). Coaches use cognitive behavioral therapy (CBT), motivational interviewing (MI), modeling, reinforcement and principles of self-efficacy to achieve effective behavior change. Common counseling strategies include open-ended questions, reflections and strategies to elicit change talk, in which participants begin to articulate reasons why they should make healthy lifestyle choices.

The evidence based tobacco cessation treatment involved 5 coaching calls to help the smoker prepare for and successfully quit tobacco. Counseling calls were supplemented with mailed support materials and an interactive web-based program. Participants were also offered cessation medications in the form of nicotine patch, gum or lozenge (NRT) free of charge according to their state or employer plan benefits. In a standard 5-call program, counseling content and call timing was tailored to each person's availability to receive calls, their quit date and specific support requested. In general, call 1 involved assessment of their tobacco use and treatment needs, encouraging the use of NRT and setting a quit date. Call 2 supported a person near their quit date. Calls 3–5 provided ongoing support for successful tobacco cessation and plans for relapse prevention.

The evidence based weight management intervention, Weight Talk,