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 different on demographics, tobacco or weight variables.

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.

A R T I C L E   I N F O

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Smoking
Weight gain
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Sequential

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
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 maintained 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,
involved 5 counseling calls, mailed materials and an interactive web-based program. For the purposes of this study, the weight-related component of the intervention aimed to prevent cessation-related weight gain, rather than to promote weight loss. Thus, the coaching goals were to reduce calories and increase physical activity sufficiently to offset metabolic slowing due to quitting smoking. Counseling content for each call is shown in Fig. 1. In call 2, Registered Dieticians (RDs) worked with participants to set an appropriate calorie reduction target. Coaches guided participants in ways to increase consumption of fruits and vegetables, reduce stress, and use the activity monitor to track and increase physical activity. Coaches educated participants about behavioral weight management techniques such as self-monitoring food intake and weight.

Healthy living counseling involved 5 calls covering health topics other than weight or tobacco. We chose to focus on sunscreen protection, flu protection, pedestrian safety, emergency preparedness and home energy savings. As shown in Fig. 1, for the standard tobacco group (contact control), coaches delivered 5 tobacco cessation calls (calls 1–5) followed by the 5 healthy living calls (calls 6–10). For the sequential group, coaches delivered the combined intervention (tobacco treatment plus weight management) in calls 1–5 which were followed by the 5 healthy living calls (calls 6–10). The 10 coaching calls were intended to last 15–20 min each.

Bachelor or Masters level coaches were trained to deliver coaching in either tobacco, weight or both. The 2 weight groups received at least 1 call from an RD. Coaches were trained to follow a call protocol but the calls were not scripted. Calls were recorded for monitoring purposes and calls from approximately 10% of participants were coded to ensure treatment fidelity.

3.5. Measures

Survey data were self-reported at registration with the quitline and during the baseline interview prior to randomization. Data collected at registration are part of the minimum dataset recommended by the North American Quitline Consortium (NAQC) [27]. Demographic data included age, gender, ethnicity, race, marital status, and education level, current symptoms of depression and anxiety and presence of a chronic disease (Chronic Obstructive Pulmonary Disease (COPD), Coronary Artery Disease (CAD) or Asthma). We used the two item Patient Health Questionnaire (PHQ-2) as a measure of depression which has demonstrated good construct and criterion validity [28]. Tobacco-related measures included number of cigarettes/day (CPD), time to first cigarette upon waking and exposure to smokers at home or work. We assessed motivation to quit with a single question: On a scale from 1 to 10, where 1 = not at all motivated and 10 = extremely motivated, how motivated are you to quit tobacco? We measured confidence in quitting with a single question: On a scale from 1 to 10, where 1 = not at all confident and 10 = extremely confident, how confident are you that you can quit tobacco? Weight related measures included height and weight, perceived expectation to gain weight (How likely do you think it is that you will gain weight as a result of quitting/staying quit using a 1–10 scale where 1 = not at all likely and 10 = extremely likely?), concern about weight gain (On a scale from 1 to 10, where 1 = not at all concerned and 10 = extremely concerned, how concerned are you about gaining weight as a result of quitting?), confidence in quitting without weight gain (On a scale from 1 to 10, where 1 = not at all confident and 10 = extremely confident, how confident are you that you can avoid gaining weight while staying quit?). The latter 3 questions were selected from two valid and reliable scales developed by Borrelli [13]. Body mass index (BMI) was calculated as the ratio of body weight to the body surface calculated using standard metric of kg/m². Participants were classified as obese, overweight or normal weight according to standard BMI cut-points of greater than 30, 25–29.9,
throughout the study and provided analytic system. Research sta
couch and participant responses were captured in the same automated
tured participant responses. Baseline data was collected by the study
participant called to enroll in the quitline. An automated system cap-
were summarized by means and standard deviations. Pearson chi-
ment.

3.7. Statistical analysis

Analysis took place in 2015–2016. Categorical variables were
summarized by frequencies and percentages, and continuous variables
were summarized by means and standard deviations. Pearson chi-
square tests for categorical variables and t-tests for continuous variables
were used to examine factors associated with enrollment in the study.
Analyses of differences across the three randomized groups included
Pearson chi-square for categorical variables and standard regression
analyses for continuous variables. Given the number of comparisons
made, we calculated false positive rates for the group.

4. Results

Our goal was to recruit 2550 smokers in 18 months from commer-
cially sponsored quitlines. Within three months, it became clear that the
volume of calls from our 10 employer groups was insufficient to meet
our target. Therefore, we added 3 state quitlines and met our goals
within the timeline. Among the 8806 adult smokers who phoned one of
the participating quitlines, 5082 (57.7%) were potentially eligible and
invited to the study. Primary reasons for being ineligible (n = 3724)
were smoking less than 10 CPD (n = 1956), having a BMI < 18.5
(n = 872), current eating disorder (n = 146), prior or planned weight
loss surgery (n = 81), having no internet access (n = 227), being unavailable
for the next 2 weeks (n = 201) or being uninterested in a
10-call program (n = 241). Callers who accepted the study invitation
were transferred from the registration specialist to a study quit coach to
complete their consent and baseline. If a coach was not immediately
available, they were informed that a coach would call them within 24 h
to complete enrollment and begin treatment. As a result of this delay,
1205 eligible participants were lost to follow up. The remainder who
were not randomized included 793 who declined the study invitation,
526 who declined the consent or baseline survey, 9 who declined ran-
odization and 9 who were de-randomized due to a technical error.
Among the 5082 eligible callers, 3084 were contacted, 2558 completed
the consent and baseline and 2540 (50% of eligible) were randomized
(844 to Control; 851 to Sequential; 845 to Simultaneous). See consort
diagram in Fig. 2.

As shown in Table 1, among the 5082 eligible smokers, those ran-
domized (versus those who were not randomized), were more likely to
be state quitter participants rather than commercial quitter partici-
pants (84.5% vs. 81.6%, p = 0.005), female (65.7% vs 54.5%,
p < 0.001), have a chronic disease (28.6% vs. 24.4%, p < 0.001), be
overweight or obese (76.3% vs 62.5%, p < 0.001), be more likely to
smoke within 5 min of waking (p < 0.01) and smoke more CPD
(p < 0.01). Groups did not differ on age, confidence in quitting or
exposure to smokers at work or home.

As shown in Table 2, randomization was successful in yielding equal
distributions across groups on demographic, tobacco and weight related
characteristics. Overall, study participants were about 43 years of age,
primarily female, overweight or obese, educated beyond high school,
exposed to other smokers and highly motivated to quit smoking with
moderate levels of confidence. Approximately a third reported they
were currently “dieting.” A majority were enrolled in state quitlines and
about 50% reported smoking a cigarette within 5 min of waking. Par-
ticipant characteristics overall and by quitter (commercial or state)
were similar to those found in other quitter studies and the general
quitter population [29–33].

5. Discussion

The main finding from this set of analyses was that nearly one third
of adult smokers seeking help to quit via national quitlines (or 50% of
those meeting the study eligibility criteria) were interested in partici-
pating in a study to help manage weight gain during tobacco cessation.
In our study, we included both genders (41% were male) as well as
individuals with low levels of weight concerns. Our rationale for not
limiting the trial to women or those with weight concerns was that
cessation related weight gain and concerns about weight gain are
common for men and women across the BMI spectrum [8,34]. Hence,
smokers who are interested in combination tobacco and weight treat-
ments may benefit from such treatment regardless of level of weight
concerns [18]. Thus, we chose a more gender inclusive enrollment
approach than that described by Spring and colleagues [25]. Another
key finding is that two thirds of our study population self-reported they
were dieting to maintain or lose weight. On average, participants ex-
pected to gain weight when they quit but were fairly confident they
could avoid gaining weight after quitting.

Our goal was to test the feasibility of this approach in a setting in
which the intervention, if successful in achieving the desired im-
provement in cessation and weight suppression, could be immediately
disseminated and widely distributed. We did not, therefore, attempt to
run an efficacy trial within this setting by introducing a waiting period
prior to enrollment. Doing so would have resulted in the enrollment of a
population more likely to be reached for follow-up calls, thereby re-
ducing the loss to follow-up.

5.1. Potential limitations

We found that the approach of adding weight management to to-
bacco cessation was feasible to administer in a quitter setting and at-
tracted smokers to sign up for this study. However, results only apply to
those who could speak English as this was an inclusion criterion.
Another limitation is that 1205 smokers who were invited to the study
were unreachable for the consent and baseline assessment and therefore
were not included in the study population. Also, although our original
intention was to test the intervention within an employed population
(commercial quitlines), the call volumes in our 10 participating com-
mercial quitlines was insufficient to recruit the large numbers needed
for the trial. Adding state quitlines enabled us to meet our recruitment
goals on time, but sampled a more prevalent real-world population of
smokers characterized by lower SES (fewer employed, fewer with
medical insurance, fewer educated beyond high school), a higher pre-
valence of obesity and higher number of cigarettes per day. Ultimately,
about 16% of study participants were recruited from commercial qui-
elines and 84% from state quitlines. State quitlines typically promote
their tobacco cessation services to uninsured or underinsured partici-
pants. With the exception of Maryland, which offers medications to all
participants regardless of insurance status, state participants must typi-
cally be uninsured or Medicare/Medicaid recipients in order to qua-
lify for enhanced NRT benefits. State benefits can vary according to
state and county and often do not provide the full recommended re-
gimen of 8 weeks of NRT due to budget limitations. In contrast, smokers
recruited from employer groups and health plans, must all be insured
to participate in their sponsored tobacco cessation program. Another po-
tential limitation is that some of the measures we used were not tested
for reliability and validity. For example, we used single items of vali-
dated measures rather than the full scale in order to reduce participant
burden and shorten the time between enrolling in the quitter and
beginning the intervention. Most of the items have been used in prior

18.5–24.9 respectively.

3.6. Data management

Registration data was collected by an ‘intake specialist’ when the
participant called to enroll in the quitline. An automated system cap-
tured participant responses. Baseline data was collected by the study
couch and participant responses were captured in the same automated
system. Research staff monitored study enrollment and data collection
throughout the study and provided analytic files at the end of recruit-
ment.
studies and are recommended by the North American Quitline Consortium (NAQC). Another limitation is that height and weight was based on self-report. People generally underestimate their weight across time points and underestimation is disproportionately greater among those who are overweight or obese [35]. Studies have shown strong correlations between measured and self-reported weight indicating that self-reported weight is an excellent approximation of actual weight across a population [36].

In conclusion, quitlines provide a natural lab for translation of new treatments into real world settings, and a majority of overweight/obese smokers calling a quitline were open to participating in a treatment addressing weight as well as smoking. Although challenges exist in recruiting commercial quitline sites (e.g. employer groups) and keeping participants engaged, the ability to successfully adapt demanding evidence-based interventions for population-level delivery could have a significant public health impact.

Table 1

| Eligible | Randomized N = 2540 | Eligible but Not randomized N = 2542 | Group comparison Statistic,p-value |
|----------|---------------------|-------------------------------------|----------------------------------|
| State Quitlines Commercial Quitlines | 84.5% | 81.6% | \( \chi^2(1) = 7.74, df = 5080, p = 0.005^* \) | \( ES = 0.077 \) |
| Gender (%female) | 65.7% | 54.5% | \( \chi^2(1) = 67.1, df = 5079, p < 0.001^* \) | \( ES = 0.230 \) |
| Age: Mean (SD) Range | 43.2 (12.2) 18-86 | 43.0 (12.6) 18-83 | \( t = 0.63, df = 4902, p = 0.53 \) | \( ES = 0.016 \) |
| First cigarette within 5 min | 50.0% | 44.4% | \( \chi^2(1) = 9.70, df = 3581; p = 0.002 \) | \( ES = 0.112 \) |
| Cigarettes/day: Mean (SD) | 20.0 (8.3) | 19.3 (8.0) | \( t = 3.1, df = 5079; p = 0.002^* \) | \( ES = 0.086 \) |
| Exposed to tobacco at home/work | 60.3% | 62.0% | \( \chi^2(1) = 1.38, df = 4223, p = 0.24 \) | \( ES = 0.035 \) |
| Chronic Disease (Any of 4) | 28.6% | 24.4% | \( \chi^2(1) = 13.9, df = 5078, p < 0.001^* \) | \( ES = 0.441 \) |
| Confidence quitting: (1-10 scale) Mean (SD) | 7.85 (2.1) | 7.71 (2.1) | \( t = 1.89, df = 3447, p = 0.06 \) | \( ES = 0.067 \) |
| BMI Mean (SD), Range | 30.0 (7.11) | 27.7 (6.23) | \( t = 11.9, df = 5080, p < 0.001^* \) | \( ES = 0.344 \) |
| % obese | 43.6% | 31.4% | \( \chi^2(1) = 218.4, df = 5080, p < 0.001^* \) | \( ES = 0.254 \) |
| % overweight | 32.7% | 31.1% | \( ES = 0.034 \) | \( ES = 0.218 \) |
| % normal weight | 23.7% | 33.5% | \( ES = 0.289 \) |
| % underweight | 0.0% | 4.0% | \( ES = 0.034 \) | \( ES = 0.218 \) |

* Significant differences < .01.

**Boldface** indicates statistical significance.

- Non-randomized group includes all those who were invited to the study but did not consent to baseline or randomization. Variables were collected during registration with the quitline.
- Asthma, COPD = chronic obstructive lung disease; CAD = coronary artery disease.
- Those who were obese were more likely to enroll and those of normal weight were less likely to enroll in the study.

Fig. 2. Best quit study CONSORT diagram.
The datasets generated during and/or analyzed during the current study are not publicly available due to the confidential nature of the data, but are available from the corresponding author on reasonable request.
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Competing interests

The authors at Alere Wellbeing declare that they are employed by Alere Wellbeing and have no other competing interests. The author at SRI International declares that he has no competing interests. The Co-PI, Dr. Bonnie Spring, declares that she has no competing interests. The Co-I, Jennifer Lovejoy, declares that she has no competing interests.

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Authors contribution

TB is the PI on the study. She collaborated with BS, JL and HJ on developing the trial design, the interventions and other aspects of the study. She drafted the manuscript, collected feedback and approval from all authors, and submitted the final version of the manuscript. BS is the Co-PI on this study, which represents an extension of her prior e-cigarette cessation work. She collaborated with JL and HJ on overseeing trial implementation, and reviewed and edited all versions of the paper. JL co-developed the Weight Talk® intervention and worked with the study team to translate the more intensive program for delivery within a 5 call program. AJT acted as grant managers and oversaw protocol development, training and implementation and administrative tasks. SM is the research assistant for the study and assisted in technological aspects of the study. KW collaborated on treatment integration, trainings, implementation and call monitoring. All authors read and contributed to the writing of this paper.

List of abbreviations

BMI body mass index
CPD cigarettes per day
NRT nicotine replacement therapy
SD standard deviation
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