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Randomized Controlled Trial of the Combined Effects of Web and Quitline Interventions for Smokeless Tobacco Cessation

Brian G. Danaher[a], **Herbert H. Severson**[a], **Shu-Hong Zhu**[b], **Judy A. Andrews**[a], **Sharon E. Cummins**[b], **Edward Lichtenstein**[a], **Gary J. Tedeschi**[b], **Coleen Hudkins**[a], **Chris Widdop**[a], **Ryann Crowley**[a], and **John R. Seeley**[a]

[a]Oregon Research Institute, 1776 Millrace Drive, Eugene, OR 97403, USA

[b]Moores Cancer Center, University of California, San Diego, 9500 Gilman Drive, MC 0905, La Jolla, CA USA

Abstract

Background—Use of smokeless tobacco (moist snuff and chewing tobacco) is a significant public health problem but smokeless tobacco users have few resources to help them quit. Web programs and telephone-based programs (Quitlines) have been shown to be effective for smoking cessation. We evaluate the effectiveness of a Web program, a Quitline, and the combination of the two for smokeless users recruited via the Web.

Objectives—To test whether offering both a Web and Quitline intervention for smokeless tobacco users results in significantly better long-term tobacco abstinence outcomes than offering either intervention alone; to test whether the offer of Web or Quitline results in better outcome than a self-help manual only Control condition; and to report the usage and satisfaction of the interventions when offered alone or combined.

Methods—Smokeless tobacco users (N= 1,683) wanting to quit were recruited online and randomly offered one of four treatment conditions in a 2×2 design: Web Only, Quitline Only, Web + Quitline, and Control (printed self-help guide). Point-prevalence all tobacco abstinence was assessed at 3- and 6-months post enrollment.

Results—69% of participants completed both the 3- and 6-month assessments. There was no significant additive or synergistic effect of combining the two interventions for Complete Case or the more rigorous Intent To Treat (ITT) analyses. Significant simple effects were detected, individually the interventions were more efficacious than the control in achieving repeated 7-day point prevalence all tobacco abstinence: Web (ITT, OR = 1.41, 95% CI = 1.03, 1.94, $p = .033$) and Quitline (ITT: OR = 1.54, 95% CI = 1.13, 2.11, $p = .007$). Participants were more likely to

Address correspondence to: Brian G. Danaher, PhD; Oregon Research Institute; 1776 Millrace Drive, Eugene, OR 97403, USA; Phone: 541-484-2123; Fax: 541-484-1108; briand@ori.org.

Declaration of interests

None declared.

complete a Quitline call when offered only the Quitline intervention (OR = 0.71, 95% CI = .054, .093, p = .013), the number of website visits and duration did not differ when offered alone or in combination with Quitline. Rates of program helpfulness (p <.05) and satisfaction (p <.05) were higher for those offered both interventions versus offered only quitline.

Conclusion—Combining Web and Quitline interventions did not result in additive or synergistic effects, as have been found for smoking. Both interventions were more effective than a self-help control condition in helping motivated smokeless tobacco users quit tobacco. Intervention usage and satisfaction were related to the amount intervention content offered. Usage of the Quitline intervention decreased when offered in combination, though rates of helpfulness and recommendations were higher when offered in combination.

Trial Registration—Clinicaltrials.gov NCT00820495; http://clinicaltrials.gov/ct2/show/NCT00820495

Keywords

tobacco cessation; smokeless tobacco; Web-based intervention; eHealth; quitline

1. Background

Approximately 8.3 million (3.1%) of U. S. adults aged 18 years and older reported last-month use of smokeless tobacco in 2013 – 93.4% of whom were male and 83.8% were White (SAMHSA, 2014), an increase from the 7.7 million smokeless tobacco users reported for 2011 (SAMHSA, 2011). Smokeless tobacco includes chewing tobacco (which typically comes in foil pouches and requires the user to chew the tobacco) and moist snuff (finely ground tobacco that comes in tins and is put between the cheek and gums but does not require chewing). Snus, a form of moist snuff that has been processed to reduce the amount of cancer-causing nitrosamine, usually comes in tins but is packaged in small tea bags that provide an easy way to use the tobacco. Smokeless tobacco does not include electronic or e-cigarettes and waterpipes. In the U. S., smokeless tobacco use is higher among men -- 7.1% vs. less than 0.4% for women. Although smokeless tobacco use is less dangerous to health than cigarette smoking (Lee & Hamling, 2009), there is evidence nonetheless that it contains “known human carcinogens” (Lee & Hamling, 2009; National Toxicology Program, 2011), and can cause cancer of the throat, stomach (Mattson & Winn, 1989), and pancreas (Alguacil & Silverman, 2004). While cigarette consumption in the U.S. is declining (Jamal et al., 2014), the marketing, sales, and consumption of smokeless tobacco have all been growing (Delnevo et al., 2014; FTC, 2013). As a result, smokeless tobacco use is a serious public health problem (USDHHS, 2012).

Meta-analyses have concluded that Web-based smoking cessation interventions are efficacious (Chen et al., 2012). In our *ChewFree* trial (Severson, Gordon, Danaher, & Akers, 2008), adult smokeless tobacco users assigned to an enhanced intervention condition (tailored content (Strecher, 2007), graphics, interactive activities, testimonial videos, and Web forums) achieved significantly greater tobacco abstinence than participants assigned to a basic static-text Web-based condition. In the subsequent *MyLastDip* trial (Danaher et al., 2013), younger smokeless tobacco users (ages 14 – 25) assigned to an enhanced Web

tobacco cessation intervention did not significantly outperform participants assigned to the basic control, although the groups showed impressive absolute abstinence at both 3- and 6-month follow-up.

Quitlines have emerged as an integral component in tobacco control efforts (Cummins, Bailey, Campbell, Koon-Kirby, & Zhu, 2007). They are able to deliver individualized, clinically rich sessions with a live counselor (Lichtenstein, Zhu, & Tedeschi, 2010). A recent meta-analysis of nine studies examining the use of Quitlines or telephone counseling for smokeless tobacco cessation (Ebbert, Montori, Erwin, & Stead, 2011) reported that smokeless tobacco users who were offered telephone counseling were twice as likely to achieve abstinence at 6 months than controls. Two of the nine studies used telephone counseling as the primary intervention (Boyle et al., 2008; Boyle, Pronk, & Enstad, 2004) whereas, in the others, telephone counseling was used as an adjunct to self-help programs as well or to more intensive interventions (e.g., dental inspection or in-person, peer-led groups) making it difficult to attribute all the success to the telephone counseling (Ebbert et al., 2011). On the strength of these results, Quitlines have been identified as an effective component in tobacco control efforts (Stead, Hartmann-Boyce, Perera, & Lancaster, 2013).

Given that Web and Quitline interventions have each shown promise for helping smokeless tobacco users quit, it is possible that their combined effect would be even greater. Currently the tobacco cessation field (smoking and smokeless) has started moving towards a dual system approach that includes a Web and quitline component: in 2014, Web-based tobacco interventions were used by more than 60% of the quitlines in the U.S. (NAQC, 2014). However, few studies have investigated the synergistic or additive effect of offering both interventions for smokeless tobacco cessation. In their analysis of 5,393 users of state-supported Web-based and/or telephone Quitline services, Puckett et al. (2015) reported that a dual tobacco cessation service offering both Web and Quitline programs might increase cessation success. In an observational study of over 10,000 smokers who called a Quitline for help to quit, Zbikowski et al. (Zbikowski, Hapgood, Smucker Barnwell, & McAfee, 2008) concluded that Web use was positively associated with tobacco abstinence rates. A smoking cessation randomized controlled trial (RCT) (Swan et al., 2010) among members of a large nonprofit health care organization examined the relative impact of three experimental conditions each of which provided participants a prescription to varenicline and the opportunity to access one of three programs: Web-based counseling, proactive telephone-based counseling by the organization's quitline, or combined web and phone counseling. Abstinence results at 3 months favored the combined web and phone counseling condition although between-group differences did not emerge at 6 months follow-up. Moreover, in a study having relevance to the current research, Graham et al. (Cobb & Graham, 2014; Cobb, Niaura, Donaldson, & Graham, 2014; Graham et al., 2013; Graham et al., 2011; Graham et al., 2014) have described results for the *iQUITT* study, a large smoking cessation RCT, that found a combination of Enhanced Web (interactive plus large social network) and Quitline outperformed both a Basic Web (static text webpages) and the Enhanced Web intervention.

In this report we used a 2×2 factorial design to examine the combined impact of access to a Web-based intervention and Quitline counseling for smokeless tobacco users who want to quit all tobacco use. Our primary hypotheses were: (a) the combined Web + Quitline

intervention would increase abstinence significantly more than either intervention alone, (b) the Web intervention would increase all tobacco abstinence, and (c) the Quitline intervention would increase abstinence. We also examined program usage and participant satisfaction of the interventions when offered alone or combined.

2. Method

2.1 Participant screening

Participants were recruited and screened online from October, 2008 to July, 2011. Because the study described in this report shared the online marketing campaign and marketing website with another research project that was concurrently recruiting young smokeless tobacco users into a cessation study (Danaher et al., 2013), prospective participants in this RCT had to be at least 25 years old. Smokeless tobacco users for the current study also needed to report they (1) used smokeless tobacco at least 1 year and consumed at least 1 can of smokeless tobacco per week; (2) self-reported smokeless tobacco as their primary tobacco type; (3) planned to quit using all tobacco use within a month; (4) resided in the U.S.; and (5) checked their email account at least once a week. Eligible individuals who then provided personal contact information, agreed to an online informed consent that described the fact that they could be assigned to any of the four conditions, and completed an online baseline assessment were randomized to condition using a computer-generated randomization vector. The research protocol was approved by the Human Subjects' Institutional Review Board of Oregon Research Institute (#FWA00005934) and University of California, San Diego (#081422).

2.2 Interventions and control conditions

Eligible smokeless tobacco users were randomly assigned to one of four study conditions (see Figure 1): Web Only (n = 421), Quitline Only (n = 421), Web + Quitline (n = 417), or a self-help materials Control (n = 424). All study participants were mailed the printed cessation guide routinely mailed to smokeless tobacco users who call the California Tobacco Chewers' Helpline – a subsidiary of the California Smokers' Quitline (California Tobacco Chewers' Helpline, 2003). Similar self-help print materials have served as active ingredients in previous smokeless tobacco cessation research (Severson, Andrews, et al., 2000; Zhu et al., 1996). Participants in the Control condition were mailed the self-help materials but were not offered the Web or Quitline counseling interventions.

2.2.1 Web Only—Participants were provided access to the fully automated, tailored, and interactive Enhanced Web-based smokeless tobacco cessation intervention used in the *ChewFree* trial (Severson et al., 2008). Program content emphasized cognitive behavioral therapy (CBT) themes and related strategies (see Figure 2) -- delivered as text, interactive activities, and videos. The program embodied a hybrid structure that combined matrix (ad-lib), tunnel (step-wise), and hierarchical (drill-down) information architecture designs (Danaher et al., 2005) that emphasized three sequential phases (planning to quit, quitting, and staying quit)."

2.2.2 Quitline Only—Participants assigned to the Quitline condition were offered proactive calls by trained counselors from the California Tobacco Chewers' Helpline. The Quitline counselor followed an effective protocol used for smokers (Zhu et al., 2002; Zhu et al., 1996) that was adapted for smokeless tobacco users. Counselors used a CATI (computer-assisted telephone interviewing) computer display that guided each call and the scheduling of follow-up calls. The initial call included discussion of motivation, quitting methods, previous quit attempts, social support, and setting a quit date. Counselors used motivational interviewing (Miller & Rollnick, 2013) to boost readiness to quit and cognitive behavioral techniques to increase self-efficacy and plan for challenging situations. They offered up to 4 follow-up calls to review the personalized plan, discuss relapse prevention, and encourage another quit attempt if needed. Other topics included health risks of smokeless tobacco use, nicotine withdrawal, dual-tobacco use, and self-image. Twenty-seven experienced tobacco cessation counselors provided the Quitline interventions: 81.5% worked full-time, 70.4% were female, and 63.0% were aged 30 or older.

2.2.3 Web + Quitline—Participants in this condition were offered both the Web content and Quitline counseling. Counselors were able to access an online dashboard on their CATI display that enabled them to review real-time metrics describing participant use of the Web intervention. This feature was intended to prompt counselors to encourage participants to use the Web program.

2.3 Measures

2.3.1 Participant Baseline Characteristics—Participants provided basic demographic information and information about their smokeless tobacco use including duration of use, daily/nondaily use, dual use of smokeless tobacco and cigarettes, and quit attempts made in the previous year. They also reported how long a can or pouch of smokeless tobacco lasted and how soon after waking up they typically used smokeless tobacco (a key item that has been found to be a good single-item measure of nicotine dependence (Baker et al., 2007)). Interest in quitting smokeless tobacco was also assessed ("Do you plan to quit chewing within a month?") and readiness to quit using the contemplation ladder (Biener & Abrams, 1991) adapted for smokeless tobacco cessation (Danaher et al., 2013; Severson et al., 2008) that used an 11-point scale with 1 = *Not ready to quit*, 3 = *Should consider quitting someday*, 5 = *Should quit but not quite ready*, 7 = *Thinking about cutting down or quitting*, 9 = *Have cut down and seriously considering quitting*, and 11 = *Ready to quit now*. Confidence (self-efficacy) in quitting was assessed using "How confident are you that you will not be using any tobacco a year from now?" with a 5-point scale: 1 = *Not at all confident*, 3 = *Somewhat confident*, 5 = *Completely confident.* Partner support was assessed using "How supportive do you expect your partner to be of your effort to quit tobacco?" with a 4-point scale: 1 = *Not at all supportive*, 2 = *Somewhat supportive*, 3 = *Supportive*, and 4 = *Very supportive*.

2.3.2 Follow-up Assessments—Online follow-up assessments were scheduled for 3 and 6 months following enrollment. Participants who failed to complete an online assessment within 2 weeks of its scheduled date were called by research staff not involved in the delivery of counseling or services. Assessments not completed within 45-days of its

scheduled date were considered *failure to complete*. Participants were mailed checks for $15 for each completed assessment and an additional $15 for completing both follow-up assessments.

2.3.3 Tobacco Outcomes—Repeated 7-day point prevalence all tobacco abstinence at both 3- and 6-month follow-up were the primary tobacco outcomes. Secondary outcomes included 7-day point prevalence all tobacco abstinence at each assessment (3 and 6 months). Smokeless tobacco abstinence was assessed in a parallel manner.

2.3.4 Program Usage—Participant engagement in Web-based interventions can be measured using multidimensional measures, often in an unobtrusive manner (Danaher & Seeley, 2009; McClure et al., 2013). We unobtrusively measured each participant's total number of Web intervention visits – and the total duration of these visits (Danaher, Smolkowski, Seeley, & Severson, 2008) – from enrollment to the 6-month follow-up assessment. A composite measure of participant engagement in using the Web intervention was based on the average of the *z* score transformation of the number and duration of website visits (Danaher et al., 2008). At the 3-month follow-up assessment, participants provided self-report data on whether they read *some* or *all* of the self-help guide. Engagement with the Quitline was assessed using data provided by counselors on the total number of Quitline calls they made.

2.3.5 Program Helpfulness, Usefulness, and Use of Other Programs—At the 6-month follow-up assessment, participants rated helpfulness of the Web content, and the Quitline calls – using a 5-point scale: 1= *Not at all helpful* to 5= *Extremely helpful*. Usefulness of the print cessation guide was assessed using a 5-point scale: 1= *Not at all useful* to 5= *Extremely useful*; and the ease of using the Web intervention was assessed using a 5-point scale: 1= *Not at all easy* to 5= *Extremely easy*. As a measure of consumer satisfaction, participants were asked if they would recommend the program to friends or family members who are interested in quitting smokeless tobacco.

Because both Web and Quitline interventions presented information about – but did not provide – NRT products, at the 6-month follow-up we asked participants whether they had used nicotine patch, nicotine gum, and/or nicotine lozenge since enrolling in the program. Similarly, they were asked about their use of smoking cessation medications Zyban® (Wellbutrin; Bupropion) and Chantix® (Verenicline). To determine the extent to which participants used non-assigned programs as recommended by Danaher et al. (Danaher, Lichtenstein, McKay, & Seeley, 2009) and Cobb et al. (Cobb & Graham, 2014), we also asked participants whether they received advice on how to quit from a health professional (physician, pharmacist, dentist/dental hygienist, and/or nurse), individual counseling (in person), group cessation program, other websites, hypnotherapy, or acupuncture.

2.4 Analyses

All analyses used SPSS statistics software, version 19.0 (IBM, 2010). ANOVA and Chi Square analysis were used to evaluate the effectiveness of randomization across the four study conditions.

2.4.1 Tobacco Outcomes—Hierarchical logistic regression analyses were used to evaluate the combined and separate effects of receiving Web content and Quitline counseling (interaction and simple effects). In the absence of a significant additive or synergistic effect (interaction), we then examined the effectiveness of each intervention (Web content and Quitline counseling) across presence/absence of the other intervention (main effects). Outcomes were calculated for 7-day point prevalence and repeated point prevalence tobacco outcomes using Intent To Treat analysis (missing cases imputed to indicate tobacco use) and Complete Cases analyses (based on individuals who completed scheduled assessments). Both analyses provided a converging view of potential treatment effects and have been commonly used in the previous smokeless cessation literature.

2.4.2 Predictors and Moderators of Tobacco Outcomes—For Complete Cases, we initially used univariate binary logistic regression to examine baseline participant characteristics as potential predictors of repeated point prevalence all tobacco abstinence at both 3- and the 6-month assessments. Significant univariate predictors were then included in a multivariate binary logistic regression using backwards elimination to remove nonsignificant variables. To identify any differential effects of the intervention on the prediction of these outcomes we included treatment condition as well as the interaction of the condition with each variable in separate logistic regression models. The order of variables was reversed in these calculations to make OR > 1.0.

3. Results

3.1 Participant Baseline Characteristics

The nationwide online marketing campaign in the U.S. recruited 1,683 participants from all 50 states and the District of Columbia: range= 1 to 156 participants per state/DC; most from Texas (n= 156) and Colorado (n= 113). Additional baseline characteristics presented in Table 1 indicated that 97.5% participants (n = 1,641) were male, 96.5% (n = 1,624) were White, they averaged 37.9 years of age (*SD* =8.2), 77.8% (n = 1,309) had used smokeless tobacco for more than 10 years, and they were motivated to quit (mean= 9.60 on an 11-point scale with 9 = *Have cut down and seriously considering quitting and* 11 = *Ready to quit now*), and were *somewhat confident* that they would be quit in 1 year (mean= 3.3 on a 5-point scale with 3= *Somewhat confident*). Seven percent of participants reported they also smoked cigarettes, and 8.0% indicated they smoked other forms of tobacco, such as cigars or pipes. Of those married and those living with a partner, 98.6% (1,266/1,284) expected to receive support from their partner. Using all characteristics (see Table 1), an analysis of condition equivalence revealed a single significant effect of participant gender ($p = .015$) due to an unbalanced distribution of the 42 women participants (2.5% of N), which was therefore used as a covariate in all subsequent analyses.

Follow-up assessment completion rates are presented in the CONSORT diagram (Figure 3). Collapsed across conditions, 75.2% of participants completed the 3-month assessment, 75.2% completed at 6 months, and 69.0% completed both assessments.

3.2 Tobacco outcomes

Participant abstinence rates by condition are displayed in Table 2 at the two follow-up assessments (3 and 6 months) and for repeated point prevalence (both 3 and 6 month). Using the more conservative repeated point prevalence measure, 27.3% to 29.5% of participants offered an intervention (Web Only, Quitline Only or Web+Quitline) were tobacco-free at both the 3- and 6-month assessment. As expected, rates of abstinence were higher for Complete Case than ITT. Rates of smokeless tobacco abstinence followed a similar pattern but achieved slightly higher rates of abstinence than all tobacco. The ITT repeated point prevalence rates achieved by condition are plotted in Figure 4.

3.2.1 Interaction and simple effects—A factorial analysis of the two interventions (Web content and Quitline counseling) revealed non-significant interaction effects using ITT analyses at 3 months (OR = .67, 95% CI = 0.44, 1.00, $p = .052$), 6 months (OR = .75, 95% CI = 0.53, 1.12, $p = .162$), and for repeated point prevalence (OR = 0.67, 95% CI = 0.43, 1.04, $p = .073$). Significant simple effects for Web Only and Quitline Only conditions were detected; each intervention was significantly more effective than the Control in terms of repeated point prevalence all tobacco abstinence: Web Only vs. Control using ITT (OR = 1.41, 95% CI = 1.03, 1.94, $p = .033$) and for Quitline Only vs. Control using ITT (OR = 1.54, 95% CI = 1.13, 2.11, $p = .007$). Similar interaction and simple effects were obtained when using Complete Cases (see Table 3).

3.2.2 Main effects—Given that a significant interaction failed to emerge between Web content and Quitline counseling, subsequent analyses examined the main effects for Web content – by collapsing Repeated Point Prevalence all tobacco abstinence results for Web Only and Web + Quitline conditions and comparing against the collapsed Quitline Only and Control conditions (see Table 4).

Results of the Web main effect analysis revealed significantly greater repeated point prevalence tobacco abstinence – but only for Complete Cases (OR = 1.35, 95% CI =1.06, 1.71, $p = .015$.). ITT results were not significant (OR = 1.14, 95% CI =0.92, 1.42, $p = .225$.). In contrast, analysis of the main effect of Quitline counseling – collapsing results for Quitline Only and Web + Quitline conditions and comparing against the collapsed Web Only and Control conditions – uncovered significant effects using both ITT (OR = 1.26, 95% CI = 1.01, 1.56, $p = .038$) and Complete Cases (OR = 1.46, 95% CI = 1.15, 1.86, $p = .002$).

3.3 Predictors and moderators of tobacco outcomes

Analyses of Baseline sample characteristics as putative predictors of tobacco abstinence revealed that repeated point prevalence abstinence (3 and 6 months) was more likely to be reported by participants who did not smoke at baseline ($\beta = -0.66$; $p = .016$; OR = 0.52, 95% CI = 0.30, 0.88), who used less smokeless tobacco at baseline (a can/pouch lasted longer) ($\beta = 0.14$; $p < .001$; OR = 1.15, 95% CI = 1.06, 1.25), who reported being ready to quit ($\beta = 0.20$; $p < .001$; OR = 1.22, 95% CI = 1.13, 1.31), and who were more confident in their ability to quit ($\beta = 0.20$; $p < .001$; OR = 1.23, 95% CI = 1.10, 1.37). Repeated point prevalence abstinence among individuals offered the Quitline intervention was more likely

reported by participants who were older (β = 0.04; p = .012; OR = 1.04, 95% CI = 1.01, 1.07) and male (β = 2.46; p = .037; OR = 11.75, 95% CI = 1.17, 123.67). Of those offered the Web intervention, daily smokeless tobacco users were less likely to achieve abstinence at both assessments (β = 1.83; p = .042; OR = 0.16, 95% CI = 0.03, 0.94).

3.4 Program usage

3.4.1 Participant use of the self-help guide—Of those participants who reported using the self-help materials, 93% (1099/1183) indicated that they read *some* or *all* of the smokeless tobacco cessation guide provided, with 12% (143/1183) reporting they read it *more than once*. No between-condition differences emerged, and self-reported use of self-help materials was not related to outcome.

3.4.2 Participant use of the Web—Unobtrusive measures indicated that the 838 participants assigned to a condition with the Web intervention spent a mean of 38.2 minutes viewing the website (Median = 17.8, SD = 77.3, Range = 0 – 862) and mean of 4.41 visits (Median = 2.0, SD = 8.7, Range = 0–92). However, almost 90% (n = 757) visited the website (Web Only 90.0%; Web + Quitline: 90.4%). Of the 757 participants who used the website, 34.6% (n = 262) visited once and 65.4% (n = 495) made multiple visits. Web Only and Web + Quitline conditions did not differ in program usage measures. For Complete Cases, participant engagement was positively related to 6-month tobacco abstinence (β = 0.47; p < .001; OR = 1.60, 95% CI = 1.28, 1.99).

3.4.3 Participant use of the quitline—Of the 838 participants assigned to a condition with the Quitline intervention, 41.4% (n = 347) participated in a Quitline call (Quitline Only = 45.6%; Web + Quitline = 37.2%). Of those that participated in a Quitline call, 9.7% (n = 81) had 1 call; 10.1% (n = 85) had 2 calls; 6.7% (n = 568) had 3 calls; 8.0% (n = 67) had 4 calls; and 6.9% (n = 58) had all 5 calls. The Quitline Only condition had a significantly greater proportion of participants with at least 1 counseling call than in the Web + Quitline condition: $\chi^2(1,838) = 6.14$, p =.013, OR= 0.71, 95% CI =0.54, 0.93. Of the 347 participants who had at least 1 call, the mean number of calls did not vary by condition: Quitline Only: *mean* = 3.13 calls; Web + Quitline: *mean* = 3.10 calls. Using the Complete Cases analysis, having at least one call was significantly related to 6-month tobacco abstinence ($\chi^2(1,561) = 7.72$, p =.005, OR = 1.61, 95% CI = 1.15, 2.26), with 6-month tobacco abstinence reported by 48% of participants received Quitline calls and by 37% of those not receiving a call.

3.4.4 Participant dual use of the Web and quitline—Of the 417 participants offered both interventions in this trial, 33.6% (n = 140) accessed both interventions, 56.8% (n = 237) accessed only the Web intervention, 3.6% (n = 15) accessed only the Quitline intervention, and 6.0% (n = 25) did not access either intervention. An examination of sample characteristics did not detect group difference by type of intervention engagement.

3.5 Program helpfulness and usefulness

Among the 757 participants who visited the Website, 85.0% reported it was helpful, 84.7% reported they would recommend the program (70.5% provided the highest rating of *Definitely will recommend*), and 96.6% indicated that it was easy to use. Participants in Web

Only and Web + Quitline conditions provided similar ratings of helpfulness, recommendation and ease of use for the Web.

Among the 347 participants who had at least one Quitline counseling call, 85.6% described the calls as helpful and 93.8% reported they would recommend the program (63.3% provided the highest rating of *Definitely will recommend*). When compared with the Quitline Only condition, participants in the Web + Quitline condition provided higher ratings of both program helpfulness ($p < .05$) and ratings of recommendation ($p < .05$).

Of the 1,147 participants who reported on the usefulness of the self-help cessation booklet, 79% described it as useful. Level of reported usefulness varied by condition ($p < .001$): Web Only (*mean* = 2.70), Web + Quitline (*mean* = 2.61), Quitline Only (*mean* = 2.49), and Control (*mean* = 2.35).

3.6 Use of other quit aids

The use of the other support or quitting aids was reported by participants who completed the 6 month follow-up assessment (n=1266): NRT product= 32% (n=410), other cessation medication= 7% (n=90), advice from a medical professional= 27% (n=337), self-help materials= 7% (n=88), other websites= 3% (n=32), individual counseling= 2% (n=29), group cessation program= 1% (n = 6), hypnotherapy or acupuncture= 1% (n = 8). Reported use of other quit aids was equivalent across conditions.

4. Discussion

Our large RCT examined the combined impact of offering a Web program and Quitline counseling for smokeless tobacco cessation. Both interventions when offered alone yielded greater abstinence than the Control (self-help booklet condition) and achieved levels of abstinence consistent with other studies. However, we found no additive or synergistic benefit of offering both the Web and Quitline interventions, as has been observed for smoking cessation (Graham et al., 2011). Although our abstinence rates for Quitline counseling are substantially higher than those typically reported for smoking cessation (Stead et al., 2013), the overall abstinence rates achieved in this trial for all groups – including the Control – are consistent with the results obtained in earlier smokeless tobacco cessation studies that used low intensity interventions (Ebbert, Severson, Croghan, Danaher, & Schroeder, 2009; Severson, Akers, Andrews, Lichtenstein, & Jerome, 2000; Severson, Andrews, Lichtenstein, Danaher, & Akers, 2007; Severson et al., 2008).

Both the recruitment procedure and the Web-based intervention used the Internet, a shared characteristic that may help to explain why participants were highly engaged (over 90% of participants accessed the Web and spent almost 40 minutes reviewing the content) and they were successful in quitting. Inconsistent with the results of Balmford, Borland, Benda, and Howard (2013) and Zbikowski et al. (2011) – this website engagement did not differ in the two Web interventions (Web + Quitline= 90.4%; Web Only= 90.0%;). It is important to note further that the level of Web visits we observed was higher than in our previous Web-based smokeless tobacco cessation RCTs (Danaher et al., 2013; Danaher et al., 2015; Severson et al., 2008) as well as reported by Cobb and Graham (2014) for smokers who called a

commercial Quitline (QuitNet.com) 25% of whom never logged into their assigned Web intervention.

One possible reason that only a third of participants used both interventions in the Web + Quitline condition is that they may have perceived concurrent multiple treatment modalities as burdensome. Offering multiple treatment modalities may prompt participants to reduce the extent to which they take full advantage of each (Danaher & Seeley, 2009). It is interesting to consider that a smaller proportion of participants completed at least 1 Quitline call in the Web + Quitline intervention (37.2%) than in the Quitline Only intervention (45.6%). It is possible that participants recruited online were actually not predisposed to receive counseling calls. In an earlier study describing treatment uptake by smokers in the California Smokers' Helpline, Zhu et al. (1996) reported that 34% (745/2189) of participants who called into the service for help to quit did not participate in a scheduled follow-up counseling call. Similarly, Cobb and Graham (2014) reported that only 27.3% (184/675) of smokers assigned to receive Quitline counseling actually received any calls. Whether smokeless tobacco users seeking help online would be amenable to telephone-based counseling has practical implications since Quitlines are increasing their online marketing and recruitment efforts (Bronars & Saul, 2009). However, our results indicate that, even with the challenge of low engagement, Quitline counseling was still effective at improving abstinence for the group overall and abstinence rates were related to receipt of at least one call, underscoring the potency of the intervention for those who received it.

Finally, it is possible that the benefits of combining both interventions might have been enhanced had the website and Quitline counseling have been more integrated and thus enhanced the supportive accountability (Mohr, Cuijpers, & Lehman, 2011). For example, although Quitline counselors in the combined treatment condition had access to an online dashboard that described participant website usage, they may not have encouraged sufficient cross-referencing of that information during calls. Similarly, the Web intervention could have provided more salient prompts to users designed to encourage them to make fuller use of Quitline counseling.

Strengths and limitations

The study had several strengths. First, we used an established online marketing webpage for smokeless tobacco cessation (www.MyLastDip.com) promoted by a Google AdWords marketing campaign in order to successfully recruit a large sample of smokeless tobacco users who wanted to quit. Second, this study used a robust 2×2 factorial design to determine that combining both Web and Quitline interventions did not improve the efficacy of either intervention when offered alone. Third, rather than relying on a single time point, we used a more rigorous measure of Repeated Point Prevalence at both the 3- and 6-month assessments. Fourth, the interventions were delivered within the context of ongoing *real-world* service. The Web intervention used an established online program for smokeless tobacco cessation (i.e., *ChewFree* (Severson et al., 2008)) and the counseling intervention used an established Quitline service (i.e., California Tobacco Chewers' Helpline). Our results support the conclusion that these effective interventions can be readily disseminated through existing Web and Quitline infrastructures.

There are several possible limitations to the current study. First, we did not biochemically validate participants' self-reported data on tobacco abstinence. However, we believe that the conclusions drawn about the interventions are sound. In general, interventions and assessments that do not include a face-to-face component have low demand characteristics and, in these circumstances, Glasgow et al. (1993) and the SRNT Subcommittee on Biochemical Verification (SRNT Subcommittee on Biochemical Verification, 2002) have supported the use of self-reported outcomes. A second possible limitation is that participation was restricted to smokeless tobacco users who were interested in quitting, who were recruited online rather than via phone calls, and who agreed to be assigned to any of the available conditions. It is possible that different results might have been obtained had the study been conducted with smokeless tobacco users who called a Quitline for help or had they been able to choose the intervention modality that they preferred. Third, it is possible that our results might not generalize to smokeless tobacco users who do not regularly access the Internet. Fourth, results of the current study may be limited to the particular design and components of the interventions we tested, or possibly the manner in which they were combined. Fifth, our study did not include a formal cost-effectiveness analysis. However, given the cost efficiencies inherent in a Web-based service, it is likely that the Web Only intervention would have lower marginal cost than a Quitline intervention -- see Graham et al. (2013). Finally, as is typically the case in Web-based interventions for tobacco cessation that don't involve some form of nicotine replacement therapy (NRTs) or prescribed medications, we did not explicitly ask participants whether they experienced any possible negative effects or adverse events associated with being involved in the study or associated with quitting smoking, as has been recommended for all Internet intervention by Rozenthal et al. (2014).

5. Conclusion

Our investigation of two smokeless tobacco cessation interventions – a Web intervention and a telephone Quitline – found that the interventions when offered alone yielded greater abstinence than the Control (self-help booklet condition) and achieved absolute levels of abstinence consistent with other studies. However, offering an intervention that combined both Web and Quitline failed to produce an additive or synergistic benefit. Program usage and participant satisfaction for the Web intervention were comparable when offered alone or with the Quitline. Interestingly, usage of the Quitline intervention was slightly lower when offered in combination, although ratings of participant satisfaction were higher when offered in combination. Overall, our results underscore the need for additional research to better understand "…the extent to which recruitment modality (i.e., Internet vs. telephone) affects treatment preference, use, and outcomes (Graham et al., 2011)."

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Abbreviations

ITT	Intent To Treat
CI	Confidence Interval
OR	Odds Ratio
ORI	Oregon Research Institute
NRT	Nicotine Replacement Therapy
SRNT	Society for Research on Nicotine and Tobacco

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Highlights

- Tobacco quitlines offer Web treatments, pointing to need for research.
- 1,683 smokeless tobacco users offered Web, Quitline, Web+Quitline, or control; tracked for 6-mo.
- Web+Quitline not found to be additive/synergistic. All treatments more effective than control.

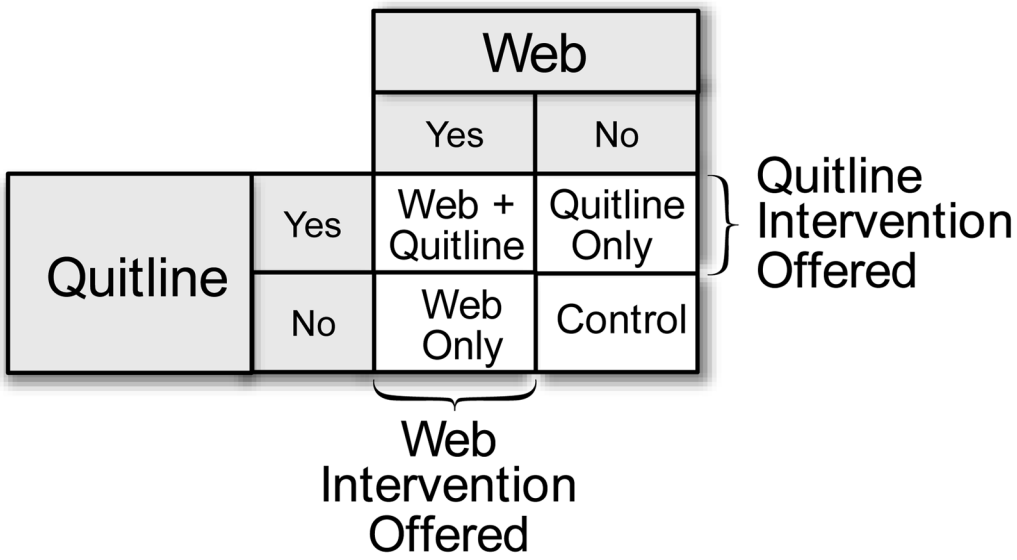

Fig. 1.
Research design

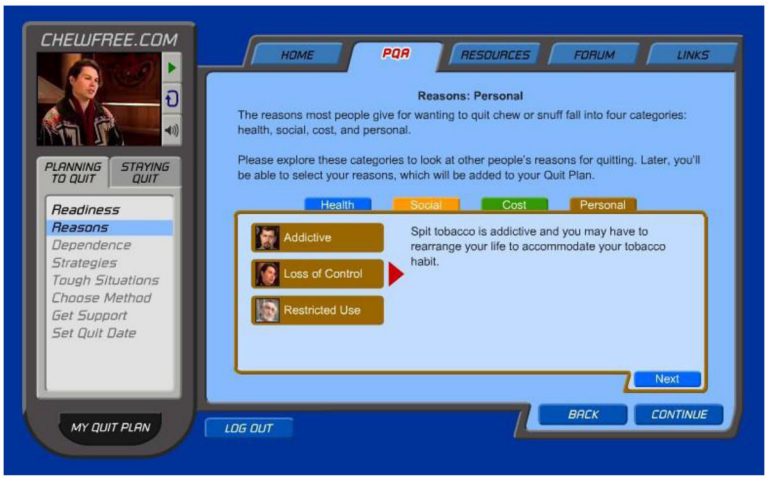

Fig. 2.
Screenshot from Web intervention

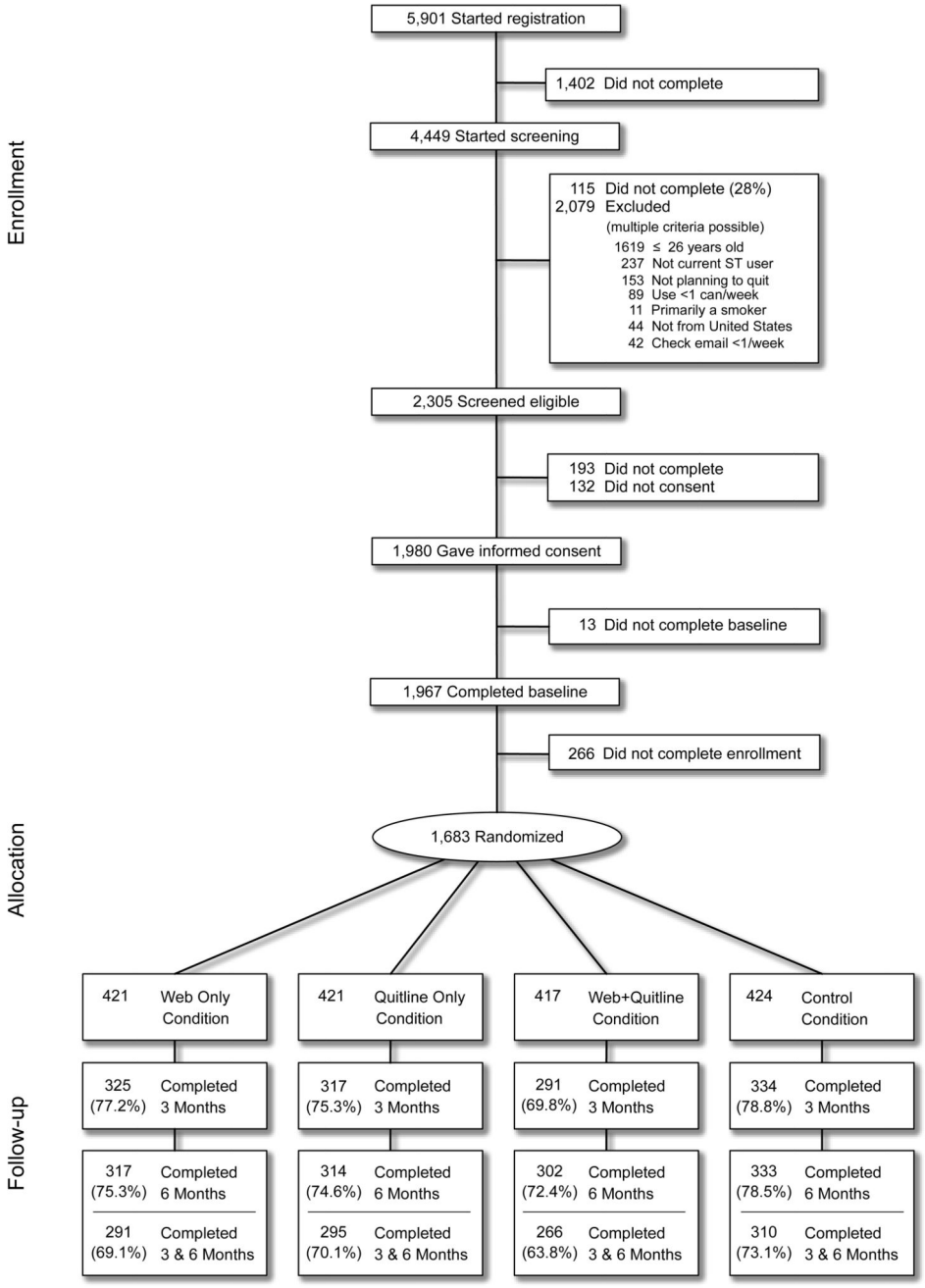

Fig. 3.
CONSORT diagram

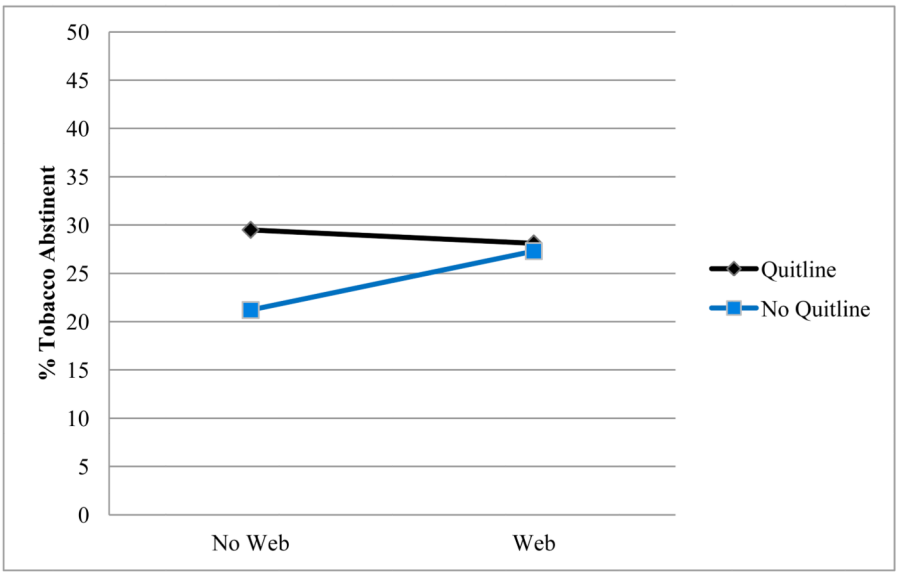

Fig. 4.

Rates of all tobacco 7-day repeated point prevalence abstinence (ITT) by condition

Table 1

Participant baseline characteristics (N= 1,683[a])

Age, *mean* (*SD*)	37.91 (8.2)
Male, *n* (%)	1,641 (97.5)
Married or living with partner, *n* (%)	1,334 (79.3)
Hispanic ethnicity, *n* (%)	21 (1.3)
Race, *n* (%)	
White	1,628 (97.2)
Black	12 (0.7)
Asian	11 (0.7)
Native American	13 (0.8)
Pacific Islander	2 (0.1)
More than 1 race	9 (0.5)
Education, *n* (%)	
Not high school graduate	28 (1.7)
High school graduate	747 (44.4)
College graduate	759 (45.1)
Post-college graduate	149 (8.9)
Use smokeless tobacco daily, *n* (%)	1,647 (97.9)
Days can/pouch lasts, *mean* (*SD*)	1.85 (1.3)
Used smokeless tobacco ≥ 10 years, *n* (%)	1,309 (77.8)
Use smokeless tobacco ≤ 30 minutes waking, *n* (%)	975 (58.6)
≥ 1 attempt to quit smokeless tobacco in last year, *n* (%)	1,175 (69.8)
Smoke cigarettes, *n* (%)	117 (7.0)
Readiness to quit, *mean* (*SD*)	9.60 (1.8)
Confidence about quitting in 1 year, *mean* (*SD*)	3.28 (1.1)
Expect support from partner, *n* (%)	1,266 (98.6)

[a]Participants could refuse to answer any assessment question. Sample size for all tabled data was 1,683 except for “expect support” for which *n* = 1,284.

Table 2

Self-reported 7-day Point Prevalence Tobacco Abstinence Rates by Condition at Follow-up Assessments (% abstinent of all tobacco)

	Experimental Conditions			
Follow-up point	**Web Only**	**Quitline Only**	**Web + Quitline**	**Control**
Intent to Treat				
3-mo.	34.7	36.3	33.6	28.5
6-mo.	37.5	37.1	36.7	31.4
Both 3- & 6-mo.	27.3	29.5	28.1	21.2
Complete Case				
3-mo.	45.1	48.3	48.1	36.2
6-mo.	49.8	49.7	50.7	39.9
Both 3- & 6-mo.	39.5	42.0	44.0	29.1

Table 3

Simple effects of Web and Quitline interventions (% self-reported abstinent of all tobacco)

	Web Simple Effect			Quitline Simple Effect		
Follow-up point	**Web Only**	**Control**	***p*[a]**	**Quitline Only**	**Control**	***p*[a]**
ITT						
3-mo.	34.7	28.5	**.044**	36.3	28.5	**.017**
6-mo.	37.5	31.4	**.046**	37.1	31.4	.088
Both 3- & 6-mo.	27.3	21.2	**.033**	29.5	21.2	**.007**
Complete Cases						
3-mo.	45.1	36.2	**.014**	48.3	36.2	**.002**
6-mo.	49.8	39.9	**.007**	49.7	39.9	**.013**
Both 3- & 6-mo.	39.5	29.1	**.005**	42.0	29.1	**.001**

[a] *p* values are reported for the simple effect of intervention type. Bold formatting highlights significant *p* values. Web *X* Quitline interactions were not significant (see text).

Table 4

Main effects of Web and Quitline interventions (% self-reported abstinent of all tobacco)

	Web Main Effect			Quitline Main Effect		
Follow-up point	**Web offered[a]**	**Web not offered[b]**	***p*[e]**	**Quitline offered[c]**	**Quitline not offered[d]**	***p*[a]**
ITT						
3-mo.	34.1	32.4	0.370	35.0	31.6	0.150
6-mo.	37.1	34.2	0.154	36.9	34.4	0.311
Both 3- & 6-mo.	27.7	25.3	0.225	28.8	24.3	**0.038**
Complete Cases						
3-mo.	46.5	42.1	0.062	48.2	40.6	**0.005**
6-mo.	50.2	44.7	**0.025**	50.2	44.8	0.053
Both 3- & 6-mo.	41.7	35.4	**0.015**	43.0	34.2	**0.002**

[a] Web Only and Web + Quitline conditions

[b] Quitline and Control conditions

[c] Quitline Only and Web + Quitline conditions

[d] Web and Control conditions

[e] *p* values are reported for the main effect of intervention type. Bold formatting highlights significant *p* values. Web *X* Quitline interactions were not significant (see text).