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Randomized controlled trial examining the adjunctive use of nicotine lozenges with MyLastDip: An eHealth smokeless tobacco cessation intervention

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ABSTRACT

Introduction: Promising Web-based interventions for smokeless tobacco cessation have emerged. We describe a randomized controlled trial (RCT) testing the relative benefits of adding the nicotine lozenge as an adjunct to the MyLastDip Web-based smokeless tobacco cessation intervention.
Methods: 407 smokeless tobacco users who wanted to quit were recruited, screened online, and randomly assigned to one of two conditions: (a) the interactive MyLastDip Web-based intervention (Web Only; $n = 202$), or (b) the website plus the offer of nicotine lozenges (Web + Lozenge; $n = 205$). MyLastDip program content is grouped according to three sequential *frames*: preparing to quit, quitting, and staying quit. If a participant reported a lapse then the program would provide tailored content on lessons learned and starting over ("retooling"). The primary outcome was 7-day point prevalence tobacco abstinence measured at follow-up assessments that occurred 3 months and 6 months post-enrollment.
Results: Assessment completion rates were 71.5% at 3 months, 72.9% at 6 months, and 65.1% for both 3 and 6 months, and did not differ by condition. Using Intent to Treat analyses, the Web + Lozenge condition was associated with a significantly higher 7-day point prevalence tobacco abstinence rate than the Web Only condition at 3 months (43.4% vs. 29.7%, $p = .004$), at the combined 3 and 6 month assessment of repeated point prevalence (35.6% vs. 23.3%, $p = .007$), but not at 6 months (44.4% vs. 35.1%, $p = .057$). Similar results were obtained for smokeless tobacco abstinence. Participants reported being satisfied with their programs and the Web + Lozenge condition participants visited the *MyLastDip* program more often ($p < .001$). A composite engagement measure of the number and duration of program visits was positively related to 6-month tobacco abstinence ($p = .009$).
Conclusions: Consistent with previous research, the MyLastDip Web-based tobacco cessation intervention encouraged long-term levels of tobacco and smokeless tobacco abstinence. The addition of nicotine lozenges significantly improved both participant engagement and self-reported 7-day point prevalence tobacco abstinence at 3 months and when considering 3- and 6-month repeated point prevalence tobacco abstinence.

1. Background

Smokeless tobacco includes use of either chewing tobacco (user chews tobacco typically packaged in foil pouches); moist snuff (finely ground tobacco not chewed but placed between the cheek and gums and packaged in tins or cans); and snus, moist snuff processed to reduce cancer-causing nitrosamines, marketed in small tea bags packaged in tins. Smokeless tobacco does not include electronic or e-cigarettes or waterpipes.

Smokeless tobacco is a serious public health problem in the U.S. (USDHHS, 2012) and it is used by almost 8 million American adults (7.1% of men and 0.4% of women) (SAMHSA, 2013). Although using smokeless tobacco is less harmful than smoking cigarettes (Lee and Hamling, 2009), both the U.S. Department of Health and Human Services (U. S. National Toxicology Program, 2014) and the World Health Organization (International Agency for Research on Cancer, 2012) have concluded that it contains known human carcinogens. For example, studies indicate that smokeless tobacco is a cause of cancer of the throat, stomach (Mattson and Winn, 1989), and pancreas (Alguacil and Silverman, 2004).

Our research group has developed and evaluated eHealth smokeless tobacco cessation interventions — the ChewFree program (Severson

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et al., 2008) and the more recent MyLastDip program (Danaher et al., 2013). Both are fully automated Web-based interventions designed to be used on personal computers, and incorporate tailored content, graphics, interactive activities, practice audios, and testimonial videos, and have used Web forums. Both programs have displayed highly encouraging results in terms of all-tobacco abstinence.

Another thrust in smokeless tobacco cessation research has examined the use of nicotine lozenges. Nicotine lozenges are part of the larger family of nicotine replacement therapy (NRT) products which have been found to increase smoking cessation treatment efficacy by 50% to 70% (Stead et al., 2012) but they have shown equivocal benefits as adjuncts to smokeless tobacco cessation (Ebbert et al., 2011). Over a number of studies (Ebbert et al., 2007; Ebbert et al., 2010a; Ebbert et al., 2009, 2010b, 2013; Severson et al., in press), our team has examined the effects and acceptability of following a regimen of using nicotine lozenges by smokeless tobacco users who want to quit. In one study (Ebbert et al., 2013) we found that using nicotine lozenges attenuated the experience of withdrawal symptoms, and this was related to greater short-term tobacco abstinence. In a more recent smokeless tobacco cessation trial (Severson et al., in press), we examined the extent to which lozenges benefited from the support provided in telephonic coach calls. Results showed that combining nicotine lozenges and phone counseling significantly increased tobacco abstinence rates compared to either intervention alone (Severson et al., in press).

This present study was informed by both of the previously described research threads — Internet intervention and nicotine lozenges. Smokeless tobacco users who sought help to quit via an Internet program were randomized to the Web condition or the Web plus the offer of free lozenges. Our hypothesis was that participants assigned to the Web + Lozenge condition would have significantly increased abstinence of all-tobacco and smokeless tobacco abstinence compared to the Web Only condition.

2. Methods

2.1. Participants

Participant recruitment for the current study occurred from January, 2013 to July, 2013. We used a nationwide Google AdWords online marketing campaign to recruit an average of 15 study participants each week until 407 study participants were enrolled. The campaign (both in online listings and content on the study marketing page) described a study that would compare the use of an online individualized (tailored) smokeless tobacco cessation program both with – and without – the use of nicotine lozenges. Individuals who indicated interest in participating pressed a button on the MyLastDip.com project marketing website to initiate the online screening procedure.

Interested individuals followed an online enrollment protocol having seven sequential steps: (1) registration, (2) screening, (3) informed consent, (4) sharing contact information, (5) baseline assessment, (6) randomization to condition, and (7) an email invitation to visit the website and offer of lozenges. The time required to complete this protocol was approximately 10–15 min.

An automated registration procedure was triggered when respondents pressed a "sign up" button on the project marketing website, which asked them to submit their email address. Respondent requests with email addresses not already in our database of the current study and our other ongoing studies were then sent an email invitation with login information to start the online screening process. In order to be eligible for possible inclusion, respondents submitting screening data indicated that they were: (1) at least 18 years old, (2) used smokeless tobacco on a daily basis for at least 1 year; (3) agreed to quit using tobacco within the next month, (4) a U.S. resident, and (5) could read English. Respondents were excluded if they endorsed any of the following: (1) used other behavioral or pharmacologic tobacco treatment programs for tobacco cessation or reduction during the previous 30 days; (2) had another household member participating in the study; or (3) reported any of a series of medical/health conditions that were precautions related to our use of nicotine lozenge: unstable angina, myocardial infarction within the previous 6 months, cardiac dysrhythmia other than medication-controlled atrial fibrillation or paroxysmal supraventricular tachycardia (PSVT), hypertension with blood pressure of $\geq$180 systolic or $\geq$100 diastolic, phenylketonuria (PKU); or currently pregnant or nursing. Individuals were also excluded whose mailing address matched one already recorded in our database of prior respondents. Individuals deemed ineligible as well as those not interested in participating were offered free access to the MyLastDip cessation program (Danaher et al., 2013), which was made freely available in a non-research mode (without assessments).

The study protocol was approved by Oregon Research Institute's (ORI) Human Subjects Institutional Review Board (approval # FWA00005934).

2.2. Study design

A randomization sequence vector was used to randomly assign eligible individuals to one of the two experimental conditions:

(1) MyLastDip only (Web Only; $n = 202$)
MyLastDip program is an engaging and interactive Web-based intervention. Program content is grouped according to three sequential *frames*: preparing to quit, quitting, and staying quit. If a participant reported a lapse then the program would provide tailored content on lessons learned and starting over ("retooling"). The program incorporated activities designed to encourage participant engagement, including the creation of a personal quitting plan. Participants were able to create personal lists (e.g., reasons for quitting), calculate how much money they would save once quit, watch videos of smokeless tobacco quitters who successfully overcame challenges to quit, listen to relaxation audios and videos, choose a quit date and method, and create a personal quitting contract (Figs. 1 and 2). The program also included a Resource section that described the ingredients of smokeless tobacco, the role of nicotine, health effects of using smokeless tobacco, prescription medications, types of nicotine replacement therapies (NRT), fake chew or herbal snuff, and links to websites that contained additional information.
Automated email reminders were sent to participants in order to encourage their use of the program. For example, if a participant did not indicate a quit date, then they were sent a reminder email to encourage them to visit the website in order to choose a quit date and benefit from other useful strategies. Supportive emails were also sent 2 days, 1 week, and 2 weeks after their quit dates. Some of the email content provided a general endorsement of the use of NRT products. Emails were also sent to prompt completion of scheduled follow-up assessments. Additional details regarding the MyLastDip program can be found in our prior report (Danaher et al., 2013). The version of the program used for the current trial was updated so that it was appropriate for use by older adults rather than the study population of 14–25 year olds in the original study.

(2) MyLastDip plus Lozenges (Web + Lozenge; $n = 205$)
In addition to being invited to use the MyLastDip program, participants assigned to the Web + Lozenge condition were mailed 2 boxes of Nicorette® Lozenges (4 mg; 108 lozenges per box). Written instructions were provided describing the tapering schedule to use for taking lozenges: weeks 1 to 6 (1 lozenge every 1–2 h), weeks 7 to 9 (1 lozenge every 2–4 h), and weeks 10 to 12 (1 lozenge every 4–8 h). During the first