ORIGINAL RESEARCH

Impact of a novel oral health promotion program on routine oral hygiene among socioeconomically disadvantaged smokers: results from a randomized semi-pragmatic trial

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Abstract
Smokers are at high risk of oral disease and report sub-optimal oral hygiene. Improving smokers’ oral hygiene could reduce their future disease risk. The purpose of this study is to assess the effects of a novel, multi-modal oral health promotion program (Oral Health 4 Life; OH4L) targeted to socioeconomically disadvantaged smokers and delivered through state-funded tobacco quitlines. Smokers (n = 718) were randomized to standard quitline care or standard care plus OH4L. OH4L recipients received a comprehensive behavioral intervention and were advised of the benefits of routine oral hygiene, encouraged to brush and floss daily (for better oral health and to manage cigarette cravings), and provided a toothbrush and floss. Participants were followed for 6 months to assess the intervention effects on routine oral hygiene (brushing and flossing) and changes in motivation and self-efficacy. Data were collected between 2015 and 2017. At 2-month follow-up, OH4L participants were more likely to meet the ADA’s recommendations for brushing twice daily (adjusted RR = 1.15 [1.04, 1.27], p = .02), flossing daily (adjusted RR = 1.20 [1.03, 1.39], p = .02), and for both brushing and flossing (adjusted RR = 1.33 [1.10, 1.61], p = .003). Daily flossing was more likely at 6-month follow-up (adjusted RR = 1.21 [1.04, 1.42], p = .02) among OH4L participants. The change in self-efficacy and motivation for daily flossing from baseline to 2 months was significantly greater among OH4L participants and mediated the intervention effect on flossing at 6 months. Integrating oral hygiene promotion with standard tobacco quitline services improved oral health self-care.

Keywords
Oral health, Oral hygiene, Tooth brushing, Flossing, Smoking, Self-efficacy and Motivation

INTRODUCTION
To maintain good oral health, the American Dental Association (ADA) [1], National Institute of Dental and Craniofacial Research [2], and other public health agencies recommend twice daily brushing and daily flossing. These recommendations recognize the importance of routine oral hygiene for disrupting and removing the plaque and bacteria that cause disease of the teeth and gums [3–5], oral pharyngeal cavity [6], and have even been implicated in systemic disease including endocarditis [7], atherosclerosis [8], and pancreatic cancer [9]. The ADA’s recommendations are grounded in empirical evidence that twice a day brushing with fluoride toothpaste is optimal for reducing the risk of caries [10–12], gingival recession, and periodontitis [13–15]. Flossing is associated with lower prevalence of periodontitis [16] and when combined with brushing, flossing helps reduce gingivitis and is more effective than tooth brushing alone [17].

Smokers are at particular risk for oral and systemic disease as a result of their tobacco use, low rates of dental care utilization, and other lifestyle risk factors (e.g., alcohol) [18–22] in addition to poor oral hygiene. Among medically insured smokers, approximately one-third (34.4%) brush less than twice a day and 72% floss less than once a day [23]. Among smokers receiving tobacco cessation services from the Washington State Quitline (many of whom are uninsured), these rates are even higher, with 42% and 80% of dentate smokers failing to meet the ADA recommendations...
for twice daily brushing and daily flossing, respectively [24]. Hygiene behaviors have also been found to vary by level of tobacco use, with heavy smokers reporting significantly worse oral hygiene than light smokers and nonsmokers [25]. Thus, smokers are an important target group for oral hygiene interventions.

To promote better routine oral care among smokers and encourage smoking cessation, we developed a theoretically-grounded, comprehensive, multi-modal behavioral intervention called Oral Health 4 Life (OH4L). The program was designed for smokers receiving cessation counseling through state-funded tobacco quitlines and consisted of behavioral counseling, supportive outreach via text messaging, and other health education materials and resources delivered in print and online. Oral health intervention content was integrated into the quitline’s standard tobacco treatment program. Like the standard quitline program, the integrated oral health content was grounded in the principles of social cognitive theory [26] and used cognitive behavioral strategies to build self-efficacy and motivation for engaging in positive oral health behaviors, in addition to promoting self-efficacy and motivation for smoking cessation. The OH4L program did not increase utilization of professional dental care during the 6 months following study enrollment, but appeared to promote smoking cessation more than the standard quitline program (the two primary outcomes) [27]. Among respondents, abstinence rates were significantly higher in the experimental arm compared to the control arm at 2-month follow-up (46.4% vs. 39.1%, adjusted OR = 1.42, 95% CI [1.01–2.00], p = .04) and retained this positive trend at 6-month follow-up (46.9% vs. 40.8%, adjusted OR 1.37 [0.95–1.96], p = .09) [27].

A secondary aim of this study was to improve smokers’ motivation and self-efficacy to improve oral health behaviors and to improve their routine oral hygiene by promoting daily brushing and flossing. We hypothesized that the OH4L program would increase both motivation and self-efficacy, as well as adherence to the ADA’s recommendations for twice daily brushing and daily flossing. Consistent with social cognitive theory, we also hypothesized that the effect on oral health behaviors would be mediated via increased motivation and self-efficacy. This article reports the findings from this secondary analysis of the OH4L intervention trial.

METHODS

The study was a collaboration between Kaiser Permanente Washington Health Research Institute, University of California, Davis and Optum Center for Wellbeing Research. All study activities were approved by the Kaiser Permanente Washington Institutional Review Board and the Western Institutional Review Board. Participants were enrolled between June 2015 and July 2016. All data were collected between June 2015 and March 2017. The study methods are detailed in the published protocol [28], main outcome paper [27], and briefly summarized below. The trial is also registered with ClinicalTrials.gov (NCT02347124).

Study design

The study used a semi-pragmatic, randomized trial design. This design blended the tight experimental control of a randomized controlled trial (RCT; e.g., standardized inclusion criteria and assessments, fidelity monitoring) with the real-world features of a pragmatic trial (e.g., usual care systems and real-world conditions) [28]. While RCTs seek to inform if an intervention can be effective when conditions are tightly controlled, pragmatic trials seek to inform if interventions are effective in the real-world [29]. By using a semi-pragmatic design we sought to validly assess the effectiveness of the OH4L intervention when delivered under real-world conditions.

Recruitment and eligibility criteria

Participants were recruited following registration with the Oregon (OR), Nebraska (NE), or Louisiana (LA) state quitlines. Callers were eligible if they reported smoking at least 5 cigarettes a day, were age 18 or older, were ready to quit smoking, could read and speak in English, were eligible for their state’s multi-call quitline program, had no dental appointment in the prior or upcoming 6 months, had at least some of their natural teeth, could receive text messages, and had internet access. Individuals were excluded if they were incarcerated, receiving inpatient substance abuse treatment, reported significant cognitive impairment or psychosis; planned to move in the next 6 months; or had a household member already enrolled in the study.

Intervention

Participants were randomized to the standard quitline program or the standard program plus multi-modal OH4L intervention (experimental arm). The standard multi-call quitline program consisted of either four or five counseling calls (depending on the state), a mailed smoking cessation guide, and access to online cessation content. It did not include any oral health promotion content. Per usual care, call timing was individualized for each person and follow-up calls were typically initiated by quitline counselors; however, participants could also call-in to request counseling when needed.

Experimental participants received the standard tobacco quitline program plus the OH4L intervention. OH4L was grounded in social cognitive theory and cognitive behavioral therapy, and was intended to promote behavior change, in part, through promoting greater motivation and self-efficacy for changing smoking cessation and improved oral health care. The intervention included scripted oral health phone counseling provided by a usual care quitline.
counselor, plus a mailed oral health promotion brochure and access to similar content online. Oral health content included discussion of the benefits of proper oral health care. Participants were advised to brush their teeth with fluoride toothpaste twice a day and to floss between teeth and near gums at least once a day. Additional content advised participants on the benefits of brushing and flossing. This was recommended as both a general strategy for better oral health care and a specific strategy for managing cigarette cravings. Strategies for overcoming commonly perceived barriers to routine brushing and flossing were also discussed with participants in order to strengthen their confidence in their ability to overcome these barriers and, as a result, build motivation for change. Participants were also advised on how to select a proper toothbrush and flossing device (i.e., string floss, interdental brushes, floss picks) and were provided a toothbrush and dental floss upon study enrollment. Counselors trained in the standard quitline intervention received additional half-day training on how to deliver the scripted OH4L content.

Participants in both randomization arms also received 16 attention-matched text messages. Among controls, messages included general health behavior tips (e.g., recommendations for diet, physical activity), but no oral health messaging. In the experimental arm, tips focused on improving one’s oral health, including encouraging daily brushing and flossing. For example, sample texts included, “Brushing your teeth twice a day with fluoride toothpaste can help fight the urge to smoke AND reduce your cavity risk. Learn more at OralHealth4Life.com.”; “Got floss? Flossing every day is one of the best things you can do to keep your mouth healthy. Learn more at OralHealth4Life.com.”; and “Want to reach for something other than a smoke after meals? Try using a toothpick to get rid of food between your teeth. Learn more at OralHealth4Life.com.” Finally, participants in both study arms could receive either a 2- or 4-week starter course of nicotine replacement therapy as part of their standard tobacco cessation protocol. Receipt of this medication was based on medical appropriateness and the financial resources of each state quitline.

Assessment
Self-reported survey items were assessed at baseline, 2 months and 6 months post-enrollment by phone with mail follow-up. Survey assessors were blinded to treatment condition.

The baseline survey included participant demographics, smoking history, and self-reported oral health and gum disease assessed using standardized items from the 2011–2012 National Health and Nutrition Examination Survey [30]. Participants were also asked how many days in the last week they used dental floss or any other device to clean between their teeth [30] and how often during the last week they brushed their teeth [31]. Response options for the latter were: not at all, once a week, every other day, once a day, twice a day, and more than two times a day. Motivation and self-efficacy for brushing, flossing, and taking good care of one’s teeth and gums were assessed using 5-point Likert scales ranging from “not at all motivated/confident” to “very motivated/confident” for each of these three behaviors. Oral hygiene behaviors, motivation, and self-efficacy were re-assessed at each follow-up survey.

Analyses
Descriptive statistics were used to characterize the sample at baseline. We used a modified Poisson regression approach to estimate the relative risk of each oral hygiene outcome for experimental participants compared with controls, adjusting for sex, age, state quitline, and baseline measures of the outcome and self-efficacy and motivation. Models were estimated using generalized estimating equations (GEE) with log link, independent correlation structure, and robust estimation of standard errors. At each follow-up, we calculated the change in motivation and self-efficacy from baseline for each individual. We then used linear regression to compare the average changes in these outcome measures by study arm using GEE with independent correlation structure and adjusting for the baseline value of the respective outcomes measure (self-efficacy or motivation), age, sex, and state quitline. Intervention effects at both 2 months and 6 months were assessed for each outcome in a single model with repeated measures for each individual, and GEE models accounted for the correlation between observations from the same individual.

To assess mediation effects of changes in self-efficacy and motivation at 2 months on oral hygiene outcomes at 6 months, we used the general framework proposed by Baron and Kenny [32]. We first confirmed an intervention effect on oral hygiene behaviors at 6 months and corresponding changes in self-efficacy and motivation at 2 months. Following the traditional approach to mediation analyses, if both these conditions were met, we then assessed mediation effects by first regressing the outcome on the exposure and adjustment variables, and compared the estimated exposure effect (total effect) with that obtained when including the potential mediator in the regression model (direct effect). If the 6-month intervention effect was attenuated by controlling for intermediate outcomes significant at 2 months, we concluded that the intervention effect was mediated by these variables. The amount of attenuation was calculated as 100*(log(Relative Risk without mediator)-log(Relative Risk with mediator)/log(Relative Risk without mediator)).

All analyses used an intent-to-treat approach with participants classified based on their assigned arm,
regardless of treatment exposure. Analyses were limited to participants who provided data at follow-up; the number of missing cases at each follow-up is presented in the CONSORT diagram, Fig. 1. All tests are two-sided Wald tests and all 95% confidence intervals and tests employ robust standard errors. We consider any test yielding a \( p \)-value of .05 or less to denote a significant difference.

RESULTS

Participants

Baseline descriptive characteristics are presented in Table 1. Participants \((n = 718)\) were predominantly female (61.8%). Three percent were Hispanic/Latino, 29.1% were Black, 12.5% were multi-racial, and 58.4% were White. Most (86.5%) had an annual household income under $40,000 and half (54.2%) had a high school degree or less education. Less than half (46.3%) were employed. Participants smoked an average of 19 cigarettes per day. With the exception of a higher proportion of non-White participants, the sample was representative of typical state quitline callers [33].

Most OH4L participants (80.2%) had not seen a dentist in more than a year, and 57.9% had not had a dental cleaning in more than 5 years. One-third (33.1%) rated their oral health as “poor,” 37.7% as “fair,” and 21.1% as “good.” Very few individuals (8.0%) rated their oral health as “very good” or “excellent.” At baseline, less than half (48.3%) met the ADA recommendations for brushing their teeth at least twice a day, 39.7% brushed once a day, and 2.7% reported not brushing at all. Twenty-seven percent reported flossing daily. The remainder either flossed less than daily (1 to 6 days a week; 34.9%) or not at all (38.1%).

On average, participants had moderate to high levels of motivation to brush twice a day (mean score = 4.63, standard deviation [SD = 0.83]), floss daily (mean = 4.03, SD = 1.34), and take good care of their teeth and gums (mean = 4.64, SD = 0.74). Participants also showed confidence in their ability to engage in these oral health behaviors,

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**Fig 1** Study CONSORT diagram. \(^{1}\)Excludes people known to be ineligible per Quitline intake data \((n = 1,072)\). \(^{2}\)Primary reasons were: No internet access \((n = 2,283)\), seen dentist in prior 6 months \((n = 1,051)\), lost all natural teeth \((n = 693)\), prior diagnosis with psychosis \((n = 373)\), no text messaging capacity \((n = 351)\), unwilling to discuss oral health \((n = 303)\), dental appointment already scheduled \((n = 233)\), and planning to move in next 6 months \((n = 170)\). \(^{3}\)Individuals ineligible and mistakenly randomized. Immediately removed from sample, not offered treatment, and not followed for data collection. Reasons for ineligibility were not mutually exclusive and included: enrolled in another study already \((n = 1)\), lived with an enrolled participant \((n = 1)\), did not own cell phone/could not receive text messages \((n = 2)\), already quit smoking \((n = 4)\), not eligible per state’s change to eligibility criteria for multi-call quitline program \((n = 12)\). \(^{4}\)Reasons for loss to follow-up were not mutually exclusive and include failure to reach participants at either 2 or 6 months. Reasons include: deceased at time of contact \((n = 2)\), too ill to participate \((n = 4)\), refused participation \((n = 28)\), and unable to be reached \((n = 213)\).
reporting high levels of self-efficacy for brushing (mean = 4.65, SD = 0.80), flossing (mean = 4.17, SD = 1.25), and taking good care of their teeth and gums (mean = 4.50, SD = 0.85).

Routine oral hygiene
At 2-month follow-up, the likelihood of OH4L participants brushing twice a day or more was significantly higher compared to the control group (adjusted RR 1.15, 95% CI [1.04, 1.27]) (Table 2). The likelihood of daily flossing was significantly higher among OH4L participants relative to control participants at both 2-month follow-up (adjusted RR 1.20, 95% CI [1.03, 1.39]) and 6-month follow-up (adjusted RR 1.21, 95% CI [1.04, 1.42]). The likelihood of meeting ADA recommendations for both daily brushing and flossing at 2-month and 6-month follow-up were similarly higher among OH4L participants relative controls. This difference was significant at 2-month follow-up (adjusted RR 1.33, 95% CI [1.10, 1.61]), but not at 6-month follow-up.

Self-efficacy and motivation
We observed a larger average increase between baseline and 2-month follow-up in self-efficacy Table 1 | Baseline characteristics

| OH4L   | Control | Overall | N = 358 | N = 360 | N = 718 |
|--------|---------|---------|---------|---------|---------|
| Female | 220 (61.5) | 223 (62.1) | 443 (61.8) |
| Hispanic/Latino | 16 (4.5) | 5 (1.4) | 21 (2.9) |

| Race       |       |         |         |         |         |
|------------|-------|---------|---------|---------|---------|
| White      | 209 (58.7) | 208 (58.1) | 417 (58.4) |
| Black      | 95 (26.7) | 113 (31.6) | 208 (29.1) |
| Other or multi-race | 37 (10.3) | 52 (14.6) | 89 (12.5) |

| Income < $40,000 per year | 294 (82.1) | 303 (84.2) | 597 (83.1) |
| Education, high school or less | 195 (54.5) | 194 (53.9) | 389 (54.2) |
| Employed, yes | 165 (46.1) | 167 (46.5) | 332 (46.3) |

| Last seen dentist |       |         |         |         |         |
| Six months to 1 year ago | 76 (21.2) | 66 (18.3) | 142 (19.8) |
| One or more years ago | 282 (78.8) | 294 (81.7) | 576 (80.2) |

| Last dental cleaning |       |         |         |         |         |
| Five or less years ago | 206 (57.2) | 210 (58.7) | 416 (57.9) |
| Greater than 5 years ago or never | 148 (41.3) | 154 (42.8) | 302 (42.1) |

| Oral health self-rating |       |         |         |         |         |
| Excellent | 1 (0.3) | 4 (1.1) | 5 (0.7) |
| Very good | 28 (7.9) | 24 (6.8) | 52 (7.3) |
| Good | 75 (21.1) | 75 (21.1) | 150 (21.1) |
| Fair | 137 (38.6) | 131 (36.9) | 268 (37.7) |
| Poor | 114 (32.1) | 121 (34.1) | 235 (33.3) |

| Brush teeth at least twice daily | 162 (45.3) | 185 (51.4) | 347 (48.3) |
| Floss daily | 89 (25.0) | 104 (28.9) | 193 (27.0) |
| Brush twice a day and floss daily | 58 (16.2) | 71 (19.7) | 129 (18.0) |

Mean (SD) | Mean (SD) | Mean (SD) |
| Age | 44.1 (12.2) | 44.5 (12.2) | 44.3 (12.2) |
| Cigarettes per day | 19.3 (9.7) | 18.9 (9.5) | 19.1 (9.6) |

Motivation

| To brush twice daily | 4.6 (0.8) | 4.7 (0.8) | 4.6 (0.8) |
| To floss daily | 4.1 (1.3) | 4.0 (1.4) | 4.0 (1.3) |
| To take good care of teeth and gums | 4.6 (0.7) | 4.6 (0.8) | 4.6 (0.8) |

Self-efficacy

| To brush twice daily | 4.6 (0.8) | 4.7 (0.8) | 4.7 (0.8) |
| To floss daily | 4.2 (1.2) | 4.1 (1.3) | 4.2 (1.2) |
| To take good care of teeth and gums | 4.5 (0.8) | 4.5 (0.9) | 4.5 (0.8) |
to floss daily among OH4L participants than among control participants (adjusted difference in changes 0.18, 95% CI [0.02, 0.35]). While not significant, we observed a similar trend at 6-month follow-up (adjusted difference in changes 0.12, 95% CI [−0.05, 0.29]). Self-efficacy to take good care of teeth and gums at 2-month follow-up and self-efficacy to brush twice daily at 2-month and 6-month follow-up also increased more on average from baseline among OH4L participants relative to controls; however, the adjusted differences between groups were not significant (Table 3).

Average increases in motivation to floss daily were significantly greater among OH4L participants relative to controls at 2 months (adjusted difference in changes 0.17, 95% CI [−0.001, 0.34]) but not at 6-month follow-up (adjusted difference in changes 0.08, 95% CI [−0.10, 0.26]). Neither motivation nor self-efficacy for brushing twice daily significantly increased from baseline to follow-up in either study arm (Table 3).

Mediation effects
Motivation and self-efficacy for daily flossing at 2 months mediated the effect of the intervention on daily flossing at 6-month follow-up separately and together, as evidenced by a reduction of about 26% to 28% in the measured association between the intervention and flossing at 6 months when change in motivation and self-efficacy at 2 months were added to the model (Table 4).

DISCUSSION
Integrating an oral health promotion program with standard tobacco quitline care was an effective strategy for improving daily oral hygiene among smokers. Participants who received the OH4L intervention were more likely to meet ADA recommendations for twice daily brushing (at 2 months) and daily flossing (at both 2 and 6 months). Self-efficacy and motivation for flossing also favored the OH4L group at 2 months and change in these constructs mediated the effects of the intervention on flossing at 6-month follow-up. Because the intervention did not have a significant effect on brushing at 6 months, we did not examine mediators of toothbrushing.

The results are consistent with prior research demonstrating the effectiveness of oral health education and promotion interventions on oral health behavior [34, 35], but expand the literature to include a specific focus on socioeconomically disadvantaged adult smokers. Most prior trials, including those demonstrating positive behavior effects, have targeted children. The current study’s focus on adults makes it unique. The study is also unique in its focus on smokers and partnership with tobacco quitlines to promote better oral health care. More commonly, dental care providers counsel smokers about quitting tobacco. We are unaware of any prior studies that have attempted to improve the oral hygiene behavior of smokers or leveraged tobacco cessation counselors to promote better oral health care. Since publicly-funded tobacco quitlines are available across the United States and counsel more than 350,000 smokers each year [36], they are an important public health resource and an ideal partner for reaching smokers.

The success of the OH4L intervention is likely due to several factors, including the fact that participants were already motivated for behavior change, as evidenced by their enrollment in their state tobacco quitline program. The intervention also encouraged daily brushing and flossing as strategies for managing cigarette cravings, in addition to the other positive oral health benefits associated with these behaviors. This may have made the hygiene recommendations more salient to participants, thereby promoting adoption. The use of multiple

Table 2: Proportion meeting recommendations for brushing and flossing at follow-up

|                  | OH4L     | Control  | Adjusted OR (95% CI) | p     |
|------------------|----------|----------|----------------------|-------|
| Brush twice a day|          |          |                      |       |
| 2 month          | 189 (69.0) | 191 (64.3) | 1.15 (1.04, 1.27)    | .006  |
| 6 month          | 174 (67.4) | 181 (68.6) | 1.04 (0.94, 1.16)    | .42   |
| Floss daily      |          |          |                      |       |
| 2 month          | 141 (51.5) | 133 (44.8) | 1.20 (1.03, 1.39)    | .02   |
| 6 month          | 132 (51.8) | 118 (44.9) | 1.21 (1.04, 1.42)    | .02   |
| Meet ADA recommendation for daily brushing and flossing | | | | |
| 2 month          | 113 (41.2) | 102 (34.3) | 1.33 (1.10, 1.61)    | .003  |
| 6 month          | 102 (39.7) | 97 (37.0)  | 1.16 (0.96, 1.41)    | .13   |

RR relative risk; CI confidence interval; ADA American Dental Association.

*All analyses adjusted for sex, age (spline), state quitline, and baseline response. The “Brush twice a day” analyses additionally adjust for self-efficacy and motivation for brushing. The “Floss daily” analyses adjust for self-efficacy and motivation for flossing. The analysis for meeting ADA recommendations for both brushing and flossing adjusts for motivation and self-efficacy for both brushing and flossing.
communication channels to educate participants about the benefits of better oral hygiene and to remind them to brush and floss daily may also have been useful, although it is impossible to determine how much of the observed effects was due to the phone counseling versus written information or the text messaging, but exposure to both of these intervention components was good. Nearly half of participants in the experimental arm (48.5%) received four or five of the counseling calls (mean calls completed = 2.9), 68.7% reported viewing the written information, and only seven experimental participants opted out of receiving text messages. In contrast, use of the OH4L website (which was optimized for viewing on computers or mobile devices) was very low. Only 9.8% of experimental participants accessed this content [27]. Given this, it appears that eHealth intervention strategies may not be optimal for reaching socioeconomically disadvantaged populations, such as those in this study. However, eHealth interventions, such as smartphone apps and mobile-optimized websites, may be an effective strategy for intervening with smokers of higher socioeconomic status and who more routinely use the internet and technology to manage their health and healthcare. This could include smokers receiving services through commercial quitline contracts paid for by their employer or health insurance.

**Strengths and limitations**

A primary strength of this study is its focus on socioeconomically disadvantaged smokers. Prior research has demonstrated that smokers have less than optimal oral health care, but this is particularly true for lower-income smokers receiving care through state-funded quitlines [23, 24]. The semi-pragmatic trial design, which blended rigorous data collection with an intervention that was delivered in a

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**Table 3** Mean change in self-efficacy and motivation from baseline to follow-up

|                        | OH4L Mean (SD) | Control Mean (SD) | Adjusted difference<sup>a</sup> (95% CI) | p     |
|------------------------|---------------|-------------------|------------------------------------------|-------|
| **Self-efficacy<sup>b</sup>** |               |                   |                                          |       |
| Brush twice daily       |               |                   |                                          |       |
| 2 months                | 0.10 (0.87)   | 0.03 (0.88)       | 0.05 (−0.07, 0.17)                       | .40   |
| 6 months                | 0.04 (0.85)   | 0.02 (0.80)       | 0.01 (−0.11, 0.13)                       | .90   |
| Floss daily             |               |                   |                                          |       |
| 2 months                | 0.20 (1.04)   | 0.09 (1.14)       | 0.18 (0.02, 0.35)                        | .03   |
| 6 months                | 0.08 (1.27)   | 0.03 (1.20)       | 0.12 (−0.05, 0.29)                       | .18   |
| Take good care of teeth and gums |   |                   |                                          |       |
| 2 months                | 0.02 (0.84)   | 0.00 (0.92)       | 0.08 (−0.04, 0.21)                       | .19   |
| 6 months                | −0.05 (0.96)  | 0.01 (0.96)       | 0.01 (−0.13, 0.14)                       | .92   |
| **Motivation<sup>b</sup>** |               |                   |                                          |       |
| Brush twice daily       |               |                   |                                          |       |
| 2 months                | 0.02 (0.83)   | 0.04 (0.91)       | −0.02 (−0.14, 0.11)                      | .78   |
| 6 months                | −0.03 (0.86)  | −0.03 (0.92)      | −0.04 (−0.17, 0.09)                      | .54   |
| Floss daily             |               |                   |                                          |       |
| 2 months                | 0.32 (1.20)   | 0.21 (1.28)       | 0.17 (−0.00, 0.34)                       | .05   |
| 6 months                | 0.19 (1.35)   | 0.12 (1.22)       | 0.08 (−0.10, 0.26)                       | .37   |
| Take good care of teeth and gums |   |                   |                                          |       |
| 2 months                | −0.11 (0.81)  | 0.01 (0.74)       | −0.10 (−0.21, 0.01)                      | .08   |
| 6 months                | 0.00 (0.77)   | −0.06 (0.77)      | 0.05 (−0.07, 0.16)                       | .40   |

Bold values indicate statistically significant at (P ≤ .05).

<sup>a</sup>All models adjust for sex, age(spline), state quitline, and the outcome measure at baseline.

<sup>b</sup>Measured on a 5-point Likert scale from “not at all” to “extremely” confident or motivated.

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**Table 4** Mediator effects of self-efficacy and motivation at 2 months on daily flossing at 6 months

|                                | OH4L Mean (SD) | Control Mean (SD) | Adjusted difference<sup>c</sup> (95% CI) | p     |
|--------------------------------|---------------|-------------------|------------------------------------------|-------|
| **OH4L vs. control**           |               |                   |                                          |       |
| Adjusted RR of daily flossing  | 1.21 (1.04, 1.42) | −                |                                          |       |
| Models with mediator(s)        |               |                   |                                          |       |
| Self-efficacy for flossing     | 1.15 (0.98, 1.35) | 26.9             |                                          |       |
| Motivation for flossing        | 1.15 (0.98, 1.36) | 25.7             |                                          |       |
| Both self-efficacy and motivation for flossing | 1.15 (0.98, 1.35) | 28.2             |                                          |       |

<sup>c</sup>All analyses adjusted for sex, age, state quitline, and baseline measures of both the outcome and the potential mediators (self-efficacy and motivation for flossing).

<sup>d</sup>% Reduction = (log(RRnomediator) − log(RRmediator))/(log(RRnomediator)) × 100.
real-world setting using actual quitline counselors, is also a strength. Because the intervention was integrated with usual care and delivered via usual care processes and procedures, it provides greater confidence that the results are generalizable. This type of semi-pragmatic research is critical for informing public health policy and helping quitline service contractors make informed decisions about which services to purchase. OH4L is not currently available as a fee-for-service, but could readily be offered if quitline service providers elected to do so.

The chief limitation of this study is our reliance on self-report to assess brushing and flossing frequency. Self-report is subject to recall bias and may not accurately reflect individual behavior, although it is the standard for assessing at-home oral hygiene behavior. We also cannot conclude how effective the intervention would be among smokers from more affluent socioeconomic backgrounds, such as those receiving tobacco quitline services through commercially funded contracts provided by employers or health insurers; although prior research suggests there is a need to intervene among this target group as well [23]. The results might also differ if smokers were targeted in contexts other than a comprehensive tobacco cessation program. Finally, because the intervention was limited to smokers who were ready to quit and eligible for comprehensive tobacco cessation services offered through the quitlines, the results may not generalize to smokers who are not ready to quit. However, individuals who are not ready to quit rarely seek cessation treatment services and, therefore, are not the target audience for an intervention like OH4L. Other strategies are needed to reach these smokers and improve their oral health care.

CONCLUSIONS

Integrating an oral health promotion program with standard tobacco quitline care improved oral health self-care in this novel randomized intervention trial and improved smokers’ motivation and self-efficacy for daily flossing. Future research should focus on strategies to ensure positive behavioral changes are sustained long-term. Public health officials and policy makers may also consider how to leverage tobacco quitlines to deliver oral health promotion interventions in the future.

Acknowledgments: This study was funded by the National Institute of Dental and Craniofacial Research (NIDCR; U01DE024462). We are grateful to many study team members at KPWHRI and Optum who made this work possible. At KPWHRI this included the Survey Research Program, Ella Thompson, Ellen Schartz, Mary Shea, Eric Baldwin, Andrew Baer, DT Tran, Deborah King, and Zoe Bernet. At Optum this included Erica Salmon, Mark Campbell, and Mona Deprey. We are also immensely grateful to the Louisiana Campaign for Tobacco-Free Living and the Louisiana Department of Health, Well-Ahead Louisiana; the Oregon Health Authority, Public Health Division, Tobacco Prevention and Education Program; and the Tobacco-Free Nebraska, Public Health Division, Nebraska Department of Health of Human Services for supporting this research. We also thank Dr. Dolphine Oda, DDS, MSc; Dr. Johnny Wang, DDS, MPH, MS; and Dr. Helga Ding, DDS, MBA, MHA for consulting on the development of the Oral Health 4 Life intervention. Finally, we are grateful to program staff at the National Institute of Dental and Craniofacial Research for their support of this research program.

Compliance with Ethical Standards

Conflict of Interest: Terry Bush is employed by Optum; the service provider of the participating tobacco quitlines. Optum has received no financial benefit from this study, but could benefit in the future if they elect to offer the Oral Health 4 Life intervention evaluated in this trial. No other authors have financial conflicts of interest with this work.

Authors’ Contributions: Jennifer B. McClure conceptualized the study, secured research funding, oversaw intervention development, and supervised study implementation. Terry Bush oversaw study activities at Optum. Melissa L. Anderson and Chloe Kraikauer conducted data analyses. Paula Blasi assisted with study implementation. Jennifer Nelson supervised implementation of the analytic plan and data management. Sheryl L. Catz assisted in the intervention development and fidelity oversight. All authors interpreted the data and prepared the article.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent: Informed consent was obtained from all individual participants included in this study.

Wellfare of Animals: This article does not contain any studies with animals performed by any of the authors.

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