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Oral health 4 life: Design and methods of a semi-pragmatic randomized trial to promote oral health care and smoking abstinence among tobacco quitline callers

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ABSTRACT

Smokers are at high risk for oral disease. As a result, they represent an important target group for population-level, public oral health promotion efforts. While dental health professionals often address smoking with their patients, no systematic efforts have been made to offer smokers an intervention to improve their use of oral health care. This paper details the rationale, design, and methods of a large, semi-pragmatic, randomized clinical trial designed to address this gap. Participants are recruited via the Oregon, Nebraska and Louisiana state-sponsored tobacco quitlines and randomized to receive standard quitline care versus standard care plus a multi-modal oral health promotion program (Oral Health 4 Life) integrated within the quitline services. All participants are followed for 6 months to assess the impact of the intervention on smoking abstinence and utilization of professional dental care. In addition, the study will assess the cost of the intervention and provide practical guidance to states on whether the intervention is financially feasible to implement, should the intervention be effective. This study protocol may be useful to others interested in promoting oral health among smokers, those interested in partnering with tobacco quitlines to extend standard services to address other high risk health behaviors among smokers, or those interested in semi-pragmatic trial design.

1. Introduction

Oral disease affects millions of people in the U.S., resulting in unnecessary pain, potential disfigurement, emotional suffering, and greater risk for morbidity and mortality [1]. Treating acute oral disease and preventing future oral disease are important public health goals. To achieve these goals, the Office of the Surgeon General [2] and the Centers for Disease Control and Prevention [1] have called for greater partnerships between the public and private sectors.

Smokers are at particularly high risk for oral disease due to their tobacco use and other lifestyle choices (e.g., low dental care utilization [3,4], poor oral hygiene [5], poor diet [6], and alcohol use [7–10]). As a result, they are a priority audience for population-level oral health promotion efforts. While prior efforts have focused on empowering dental providers to promote tobacco abstinence, dental professionals often have limited time, resources and training to provide behavioral counseling, and their efforts fail to reach individuals who do not visit a dentist. Moreover, many dental professionals are not trained in behavioral counseling and simply providing oral health education alone does not result in lasting behavior change [11–16].

A complementary strategy for reaching smokers, particularly those not routinely seeking dental care, is to integrate oral health promotion into tobacco quitline programs. Quitlines provide behavioral counseling for tobacco cessation, primarily through proactive calls (i.e., calls initiated by the quitline on a pre-determined schedule) with supplemental outreach via online materials, mail, and/or text messaging. Quitlines are available in all U.S. states and are an effective public health intervention for smoking cessation [17–20]. In 2015, an

Abbreviations: OH4L, Oral Health for Life; QD, quit date; CBT, cognitive behavioral therapy; PPA, point prevalent abstinence; NRT, nicotine replacement therapy; KPWHRI, Kaiser Permanente Washington Health Research Institute; AW, Alere Wellbeing; UCD, University of California, Davis; DSMB, Data and Safety Monitoring Board; NIDCR, National Institute of Dental and Craniofacial Research

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estimated 1% of the 40 million U.S. smokers received care through a state-sponsored quitline [21]. This equates to approximately 400,000 smokers, the majority of whom are female (57%) and have less than a college degree (57%). A significant portion of these callers receive Medicaid (38%) or are uninsured (22%) [21]. Based on the reach of the quitlines, we hypothesized that partnering with them may be an effective strategy to reach smokers and promote better oral health care. In preliminary research, we found many quitline callers do not seek routine dental care [5], so there is a need for intervention. We also found that quitline callers and the key stakeholders responsible for funding and providing these services were supportive of this intervention concept [5,22,23].

Thus, we developed a theoretically-grounded, comprehensive, multi-modal behavioral program (Oral Health 4 Life, OH4L) to promote better oral health care in conjunction with standard tobacco quitline counseling. The program consists of behavioral counseling, supportive outreach via text messaging, and other health education materials and resources delivered in print and online—all designed to fit within the quitline infrastructure. By partnering with state quitlines, the program can reach a high-risk, high-need, lower-socioeconomic status audience.

This paper describes the rationale, design, and methods of the OH4L study. At the time of this writing (October, 2016), recruitment has ended, but intervention delivery and data collection are ongoing and expected to be complete in March 2017. Study findings are not presented in this paper, but will inform the cost and effectiveness of the OH4L intervention. This study could serve as a model for leveraging the tobacco quitline infrastructure to address other high-risk health behaviors among smokers nationwide.

2. Methods

2.1. Collaborating sites and oversight

This study is a collaboration between researchers at the Kaiser Permanente Washington Health Research Institute (KPWHRI), University of California at Davis (UCD), and Alere Wellbeing (AW). At the time the study was initiated and data collected, KPWHRI was known as the Group Health Research Institute. The intervention was developed by KPWHRI and designed to be integrated into standard quitline services provided by AW, the leading provider of tobacco quitline services in the United States. AW treats approximately 350,000 thousand smokers each year across 25 state quitline contracts. All phone-based counseling in the study is provided by AW. Mail and text message-based intervention content are provided by KPWHRI, and all follow-up data collection is conducted by KPWHRI's Survey Research Program. Treatment fidelity monitoring is conducted by KPWHRI, under the supervision of staff at UCD.

The OH4L trial is funded by the National Institute for Dental and Craniofacial Research (NIDCR) and is registered with ClinicalTrials.gov (NCT02347124). All research activities were reviewed and approved by the KP Washington Institutional Review Board. Recruitment and treatment activities at AW were also approved by the Washington Institutional Review Board and study participation was approved by authorities in the Oregon, Louisiana, and Nebraska state departments of health who contract quitline services with AW. The project is overseen by a Data and Safety Monitoring Board (DSMB) convened by NIDCR and an NIDCR medical monitor.

2.2. Study objectives

The primary objective of this study is to assess the effects of the OH4L program on tobacco abstinence and utilization of professional dental services. Both outcomes are considered primary because quitline stakeholders told us the intervention would only be viable to implement if improving oral health care did not deter from cessation [23].

Secondary objectives include: a) assessing the impact of the OH4L program on key secondary behavioral outcomes and select intermediate outcomes/process measures that could mediate treatment effects, and if warranted based on the results, b) calculating the incremental cost of the OH4L program, and c) providing these data to key stakeholders to inform decisions about whether the OH4L program warrants dissemination in its current form or further refinement and evaluation. Relevant details to these objectives are discussed in the following sections.

2.3. Pragmatic design

On the continuum of explanatory to pragmatic trials, this study uses a semi-pragmatic trial design. Explanatory studies are randomized trials conducted under idealized conditions with tight experimental control. In contrast, pragmatic trials evaluate interventions using usual care systems and real world conditions [24]. While explanatory studies seek to inform if an intervention can be effective when conditions are tightly controlled, pragmatic trials seek to inform intervention effectiveness in the real world [25]. The latter is more useful when informing clinical and policy decisions.

Loudon et al. [24] have offered a Pragmatic-Explanatory Continuum Indicator Summary (PRECIS-2) to help researchers make study design decisions that align with the goals of their trial. The tool describes a continuum between explanatory and pragmatic study designs using nine domains: (1) the extent to which participants are similar to usual care recipients, (2) the amount of extra effort required for recruitment beyond usual care activities, (3) how closely the setting matches usual care, (4) how well the organizational resources for intervention delivery match usual care, (5) flexibility of the intervention delivery compared to usual care, (6) flexibility in how participants are monitored and the intervention adhered to compared to usual care, (7) how the intensity of follow-up data collection compares to usual care; (8) relevance of the primary outcomes to participants, and (9) extent to which all data are included in the primary outcome analyses. Each domain is scored on a five point scale from 1 (“very explanatory”) to 5 (“very pragmatic”). Using this framework, the current project scores 36 out of 45 points, reflecting a more pragmatic trial. This score was derived based on the following characteristics and their associated domain scores: (1) participants are actual smokers seeking usual care, although some callers are screened out (score = 4); (2) no extra effort is required to identify and recruit quitline callers (score = 5); (3) the setting is a real-world tobacco quitline (score = 5); (4) the organizational resources for the intervention were identical to usual care resources (score = 5); (5) the standard care quitline intervention was not changed, but experimental participants received additional oral health services (score = 3); (6) a higher level of fidelity monitoring was included in the study design, but real world practices were used to provide feedback to quitline counselors (score = 3); (7) usual care includes phone-based follow-up assessments of smoking cessation, but with less intensive effort to retain individuals than in this study (score = 2); (8) smoking cessation and oral health are relevant outcomes for usual care quitline callers, although most are only seeking assistance quitting smoking when they enroll in services (score = 4); and (9) all participants and data collected will be included in main outcome analyses (score = 5). Thus, the resulting semi-pragmatic trial blends the best aspects of both explanatory and pragmatic trial designs.

2.4. Recruitment and eligibility criteria

Participants were recruited from the Oregon, Nebraska, and Louisiana State Quitlines. Each state was chosen because they contract services with AW, offer a multi-call standard tobacco counseling program, and have affordable dental care services to which participants could be referred for care.

Recruitment occurred from June 2015 through July 2016. Callers to each participating quitline were first pre-screened in real-time using