TILE OF RESEARCH: Reducing Prescription Opioid Misuse: ROPEs Pilot Trial

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Statistical Analysis Plan

Data for the pilot trial phase of this study will be obtained from online self-report measures and web-analytic metrics. Data will include: (1) recruitment rates; (2) time to complete ROPEs intervention and completion rates; and (3) follow-up assessment rates; as well as changes in dentists' knowledge regarding: (1) role in curbing prescription opioid misuse, initiation to abuse, and diversion; (2) recent released guideline recommendations for standard pain management in dental practices; and (3) risk mitigation strategies, such as prescription opioid misuse screening and use of their state's PDMP. Web analytic metrics will include time spent on the site, number of log-ins, and activity completion. The participant will directly enter data into the web-based platform during completion of ROPEs (or attention control). Assessment (pre-intervention, post-intervention, one- month follow-up) data for this study will be stored electronically in de-identified manner using participant identification numbers (USERID).

The first primary outcome is methodological feasibility as assessed by recruitment rate. Recruitment rate is defined as the number of individuals/participants enrolled and randomized to either intervention or control out of the number of individuals expressing interest/provided log-in credentials. As this is an online intervention (with online control), randomization occurs simultaneous to enrollment when the participant uses provided credentials to log in to the site. Recruitment will be reported overall and by group (ROPEs vs. control).

The second primary outcome is methodological feasibility as assessed by intervention (ROPEs) and control condition completion rates. Completion rate is defined as the number of enrolled participants who complete the content for either the ROPEs intervention or the control condition. Completion rates will be reported overall and by group (ROPEs vs. control).

The third primary outcome is methodological feasibility as assessed by follow-up completion rates. Follow-up completion is defined as the percent of enrolled participants who complete the one-month follow-up survey administered via RedCap. Follow-up completion rates will be reported overall and by group (ROPEs vs. control).

The fourth primary outcome is methodological feasibility as assessed by time to complete the intervention. Time to complete intervention is defined as the average (standard deviation) number of minutes it takes participants to complete either the ROPEs or control content. Time to complete the intervention will be reported by group (ROPEs vs. control).

The secondary outcome is change in knowledge regarding practice recommendations for opioid prescribing in the dental setting. The Knowledge Change Questionnaire was developed specifically for this study and contains five items that assess dentists' knowledge regarding: (1) dentists' role in curbing prescription opioid misuse, initiation to abuse, and diversion; (2) recent released guideline recommendations for standard pain management in dental practices; and, (3) risk mitigation strategies, such as prescription opioid misuse screening and use of their state's PDMP. One point is awarded for each correct response to items on the questionnaire. The questionnaire scale ranges from 0 (no correct items, least knowledge) to 5 (all correct items, most knowledge).

The Knowledge Change Questionnaire will be administered at three time-points: (1) immediately pre-intervention; (2) immediately post-intervention; and, (3) one- month post-intervention. We will make a direct comparison of the efficacy of the ROPEs intervention versus the attention control in increasing knowledge of risk mitigation strategies: (a) from pre-test to post-test and (b) from pre-test to one-month follow-up. We hypothesize that ROPEs, in comparison with controls, will result in significantly greater change in knowledge regarding recommended risk mitigation strategies. This outcome will be assessed using one-way ANOVA analyses. The independent variable will be intervention assignment.

It is important to reiterate that the primary aim of the pilot RCT is to demonstrate the feasibility of methodology. We do not anticipate the pilot to be adequately powered to produce meaningful between-group differences in knowledge change.