Title: Development and Evaluation of a Theory and Evidence-based Intervention to Reduce Hazardous Alcohol Consumption Among Treatment Seeking Smokers

NCT number: not yet assigned

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Project background

We will measure the adoption of the alcohol resource in the patient portal by examining analytics data, which will be passively collected by the STOP patient portal. Given the evidence supporting the digital alcohol interventions that will adapted for this population, and the larger sample that would be needed for an efficacy study, we will not directly evaluate the efficacy of the intervention in this study.

Specifically, we will test whether more eligible STOP patients accept the alcohol resource with the patient portal than did when it was offered by health care providers in the COMBAT, the cluster randomized control trial we conducted previously. In that study, 52.7% of participants scoring 8+ on the AUDIT-10 received an offer and 15.4% (95%CI = 13.9%, 17.1%) of the total sample (29% of those receiving an offer) accepted it. Reanalysis of COMBAT data showed that patient characteristics were minimally predictive of offer receipt and acceptance, while provider-level variance was substantial in both cases (ICCs>=0.50). This suggests that provider willingness to offer the intervention was the primary reason for the moderate offer proportion. In this study, we anticipate a similar acceptance rate, but will make the offer to all participants, yielding an anticipated acceptance rate of 29%.

Outcomes

Our primary outcome is **acceptance of the offered intervention**, defined as a response of 'yes' to the question, "Are you interested in receiving some information about alcohol and smoking and about ways of reducing alcohol use?"

Our secondary outcome is **continued participation in smoking cessation treatment.**

Analysis plan

Primary outcome: We will analyze the primary outcome using a chi-square test comparing the proportion in the present study to that in the original COMBAT project. We will use a significance level of 0.05 and will derive confidence intervals around both proportions and around the difference between them.

Sensitivity analysis: To examine the potential sensitivity of this result to case-mix differences, we will use logistic regression to compare adoption in this sample to that among COMBAT participants with AUDIT scores of 8 or higher. Due to the small size of the sample in the current study, we will use propensity score weighting to adjust for age, gender, heaviness of smoking, AUDIT scores, education, income, and comorbid conditions. To account for sporadic missingness in these variables, we will use multiple imputation, with the number of imputed datasets dependent on the observed level of missingness.

Secondary outcome: For our secondary outcome, we will compare the proportion of participants who do not attend a clinical visit after self-enrolling to that among people self-enrolling before the study began who would have met study criteria. We will not examine longer-term retention due to the study timeline and the expectation that effects would be visible at the first contact.