Single-arm pilot trial analytic plan

NCT05365633

"Empowering sexual and/or gender minority tobacco cessation: A pilot study"

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Sample Size/Analysis Plan. Primary outcome variables will be: retention, perceptions of the intervention, adaptive coping strategies, biochemical verification of tobacco abstinence at 12 weeks post-quit-date, and treatment adherence. We will evaluate retention by calculating the proportion of participants who complete the final study visit at 12-weeks post-quit, with the goal of retaining >80% of participants. We will qualitatively evaluate perceptions of the intervention (as described above). We will use a two-sided paired samples t-test to examine the mean differences in adaptive coping strategies pre- and post-intervention (α=0.05). Assuming a standard deviation of differences of 4.0[80] we will have 80% power to detect a mean difference of 2.6 in adaptive coping strategies. Tobacco cessation outcomes will be considered successful if the proportion of participants with biochemically-verified smoking abstinence (expired carbon monoxide) at 12 weeks post-quite-date is equal to or greater than the general TTRP intervention (i.e., 18% at 12 weeks[42]). Treatment adherence will be considered successful with moderate/optimal medication and counseling adherence >50% of treatment weeks.

Expected outcomes. Empowerment-enhanced tobacco cessation assistance will be acceptable and feasible (Aim 1), will increase within-subject empowerment outcomes (Aim 2), and will meet benchmarks for tobacco cessation outcomes (Aim 3).