

Pilot Testing a Digital Intervention to Improve Smoking Cessation in Persons With Serious Mental Illness

Statistical Analysis Plan

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Provide the rationale and sample size calculations for the proposed target population: Treatment development guidelines usually consider small-scale (Stage 1b) pilot trials to have 30-60 participants. We will increase this number because of the nature of the population. Not all participants will remain abstinent, set a quit date, or have significant interaction with the platform. In addition, follow-up rates for web-based SC trials are lower than in face-to-face pilot RCTs. Therefore, a sample of $n=90$ for the pilot trial (45/arm) will provide adequate numbers for feasibility and acceptability analyses. Our primary objective is to determine whether EX-SMI shows promise, rather than to determine statistical significance between groups at certain p values. We are cognizant of the pitfalls of relying exclusively on small-scale pilots to determine the promise of novel treatment approaches. Effect size estimates with small samples have a large standard error, and we primarily will be hoping to find a pattern of results that is supportive of the BC+EX intervention. Our data also will allow us to obtain stability estimates for point-prevalence abstinence from smoking and changes in target mechanisms. Relatively small effect sizes may still have clinical importance given how many people can be reached with this modality and its scalability.

Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study: Preliminary data analyses will include studies of randomization effects (group differences), patterns of missing data, follow-up completion rates, distributional properties of dependent and other measures, and correlations among outcome measures. Frequency and contingency tables and univariate and bivariate plots will be generated. These informal plots and summaries will allow us to be cognizant of data distribution characteristics before building regression models. All models will include number of days in the hospital, use of NRT post discharge, and BSI total as covariates. In addition, if by chance there is an important variable significantly out of balance between conditions (e.g., symptom severity), we will include it in the main models. Hypothesis 3a (Feasibility and Acceptability): Feasibility and acceptability analyses will mirror processes used in Aim 2 (C.5.g.) but account for between arm comparisons. We will examine (1) actual recruitment compared to recruitment goals; (2) length of time to approach participants on the inpatient unit; (3) time to registration on EX-SMI in the hospital; (4) follow-up completion rate; and (5) feasibility of completing biochemical verification of abstinence. These metrics will be used to compare the feasibility and acceptability of EX-SMI as compared to the comparison condition, the extent to which EX-SMI can be routinely integrated into the inpatient setting, and our ability to conduct a formal efficacy trial in an adequately-powered RCT. Acceptability analyses will compare BC+EX vs BC scores on the CSQ-8 and the SSS-30, and analysis of treatment engagement following hospital discharge. Hypothesis 3b (Efficacy): A higher proportion of participants randomized to BC + EX will self-report 7-day point prevalence abstinence at 3 months post-discharge than in BC. Smoking abstinence will be analyzed with logistic regression at each time point (1- and 3-months post-discharge) with intervention condition and the covariates described above as independent variables. These analyses will be run both as a completers analysis and with missing=smoking. The test of the hypothesis will be the test of whether the coefficient for condition is significantly different from 0. Hypothesis 3c

(Target mechanisms): Reductions in craving and increases in self-efficacy and motivation at 1 month in BC+EX compared to BC will mediate increased SC in the BC+EX condition compared to BC at 3 months. Sample size in this Stage 1b trial precludes formal mediation analysis with adequate precision. The analyses are designed to test the plausibility of target mechanisms of EX's effects on smoking outcomes. Our focus will be on change in mechanisms assessed at the 1-month follow-up. We will first test whether treatment condition predicts differences in these variables. We will then enter these potential mediators into the logistic models predicting smoking abstinence at 3 months along with covariates noted above and treatment condition. We will be able to examine whether the effect of treatment is reduced when the mediators are added to the model and can test for significance (not expected given the sample size) using the products of coefficients method.