Study Analysis Plan

Positive Psychotherapy for Smoking Cessation Enhanced With Text Messaging: A Randomized Controlled Trial

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Analysis Plan

Initial analyses will use chi-square tests to examine group differences in biochemically-validated, 7-day point prevalence smoking abstinence at each follow-up as well as continuous abstinence across follow-ups. The primary outcome analysis will utilize Generalized Estimating Equations [1, 2] to test the effect of treatment condition on abstinence at 12, 26, and 52 weeks post quit date. GEE is a method of repeated measures analyses for categorical and continuous outcomes that allows for appropriate modeling of covariance structures when observations are correlated across time [3]. The primary, between groups, independent variable in the analysis is treatment group assignment. ST+ will be used as the reference group in this model. The model will contain a linear effect of time as well as the variables included in the urn randomization—gender, cigarette dependence, and CES-D PA—following clinical trial analysis recommendations [4]. A second step will test the interaction between treatment condition and time to determine whether relative effects of PPTS+ change over time.

We will also determine if intervention engagement, reduced attraction to smoking, or greater self-efficacy mediates the relationship between PPT-S+ and smoking behavior. A regression analysis will be performed predicting the mediators at session 6 (note that the self-report measures assess strategies used during the quit attempt retrospectively, while attraction and self-efficacy refer to the current moment). Additionally, we will run a second model which adds the mediators to the main effects generalized estimating equations model testing outlined in the previous paragraph. We will use the asymmetric products of coefficients method to calculate the significance of this indirect effect and its 95% confidence interval using the RMediate program [5, 6]. Mediators will be tested sequentially such that strategies will be entered first followed by reduced attraction to smoking and self-efficacy, which serve as more proximal mediators. Follow-up analyses will examine individually each of the four core PPT-S strategies to isolate whether either of these are more important to outcomes.

We will also test whether PA moderates the effect of PPT-S+ on smoking outcome. To do this, we will add to the model testing an interaction term between PA and PPT-S+. Given a significant interaction, follow-up analyses will establish whether there is a crossing point of PA level at which PPT-S+ is not likely to be more effective than ST+. Analyses will be repeated with the CES-D total score as the moderator.

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4. Moher, D., et al., *CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials.* BMJ, 2010. **340**: p. c869.
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