Engaging Working Memory and Distress Tolerance to Aid Smoking Cessation

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Analytic Plan

Note: Due to limited sample size the full analytic plan for this project could not be enacted validly.

Analyses for outliers, non-normal distributions, nonlinear relations, and influence statistics will be conducted; data transformations will be considered where appropriate. We will analyze data using mixed effects regression models (MRM) because they allow inclusion of all participants regardless of missing data (which improves power and generalizability) and are the recommended method for longitudinal data analysis (Hamer & Simpson, 2009). For each analysis, the distribution of the DVs will be evaluated and appropriate linking functions and outcome distributions will be used if the DVs are not normally distributed (in these cases the analysis will be generalized linear mixed models). For all analyses, the following baseline assessments will be included as covariates in the analyses: cigarette use in the last 30 days, FTCD score, QSU score, BRIEF-A scores for the Behavioral Regulation Index, and psychological distress from the K6+ symptoms.

Aim 1. We will perform repeated-measures MANCOVAs using MRMs. IVs will be intervention condition (3 levels) and assessment context (smoking vs. deprivation; 2 levels). One MANCOVA will be performed for each of the three risk categories (stress reactivity, WMC, DT) with the multiple measures of each risk factor being the multivariate DVs. For Aim1a, we will use contrasts to test whether Mindfulness and Mindfulness+IE will each significantly improve stress reactivity, WMC, and DT relative to the control condition (CC), during the standard smoking assessment. For Aim 1b, we hypothesize that Mindfulness+IE will significantly improve stress reactivity, WMC, and DT relative to both the Mindfulness and CC conditions, during the smoking deprivation assessment.

Aim 2: For Aim 2, we will examine the bivariate associations between the triple risk variables and McLee Lapse outcomes. We will attempt to balance the need to determine which individual variables at which assessment context are related to which outcomes, with the need to minimize the number of tests. Thus, multivariate MRM (MMRM) will be used with the 2 McLee Lapse outcomes as the multiple DVs. One MMRM will be performed for each individual risk variable, with the IVs in each MMRM being the 2 assessments (smoking context and deprivation context) of the individual risk variable. This MMRM will be compared to the same MMRM that constrains the coefficients of each IV to be equal. If the likelihood ratio test indicates that the constrained model does not fit the data worse than the unconstrained model, then the relation between the risk factor and the outcomes does not differ by assessment context. If the test is significant, assessment context would be considered a moderator of the relation between the risk factor and outcome. Further, we will include a dummy variable to differentiate the 2 outcomes (0=latency, 1=number of offers of cigarettes resisted). If an interaction between that dummy variable and an IV regression coefficient is significant, the relation between the risk factor and outcome is different for the 2 outcomes.

Aim 3: To determine which of the individual risk assays are related to outcomes over and above the other factors, including consideration of the assessment context of each risk factor, we will perform analyses similar to the MMRM in Aim 2 with the following differences: 1) if Aim 2 shows that the relation between a risk assay and outcomes did not differ by context, the 2 measures of the risk factor will be averaged across the 2 contexts and used as a single predictor, and 2) all the risk factors will be entered as simultaneous predictors of outcomes. Non-significant predictors will be dropped and the analysis rerun.

Exploratory Analyses: 1) In consideration of sex as a biological variable, sex and the interactions between sex and all predictors will be considered in exploratory analyses for each Aim. 2) We will examine whether ASI moderates the effects of treatment condition and context (stress) on the risk categories in Aim 1, by adding ASI and its interaction with the treatment condition and context to the MMRMs in Aim 1. 3) We will examine smoking topography as a predictor of outcomes in Aims 2 and 3. 4) We will examine number of intervention sessions attended and dropouts to aid data interpretation and future study planning.

Power Analysis. We used PinT 2.12 (Power in Two-Level models) to calculate the smallest effect size detectable given our N=75 at the deprivation assessment. Since no power analysis programs are available for multivariate MRM, we performed power analyses for the univariate MRMs knowing that power for the multivariate MRMs will be greater.[108] PinT indicated that we had greater than .80 power to detect an effect size of *d* =.40 for **Aim 1,** *d* =.39 for **Aim 2,** and *d* =.48 for **Aim 3.** As per research detailed above,[54,63,64,71,82,109] there is preliminary evidence indicating that our interventions have the ability to activate mechanistic targets, and for mechanistic targets to be related to clinical outcomes, at effect sizes beyond these powered values.