Brief Intervention for Justice-Involved Substance Users: Harnessing Mechanisms of Change

NCT03308877

04/01/2017

D.7. Data Analysis. A baseline check of randomness will be conducted for each variable collected. Categorical variables will be analyzed using chi-square tests; continuous variables with ANOVAs. To assess Hypothesis 1 continuous outcomes, Analysis of Covariance will be used. The effects of BMI+SC on commitment to change, self-regulation, and substance use will be assessed immediately following intervention. Longer term substance use effects will be examined at 6-month follow-up. For substance use toxicology results, logistic regression will be used. In all instances, alpha = .05; covariates will include gender, race, age, and the outcome baseline score of interest as well as any other variables found to differ at baseline. Additionally, effect sizes will be examined using marginal means.[71] Structural equation modeling (SEM) will be used to test the hypothesis that the effect of BMI+SC on substance use will be mediated by increases in commitment to change and self-regulation (Figure 2).[72] *Substance use status* at six month follow-up is the key outcome of interest. We hypothesize that effects on six month substance use are mediated, in part, by BMI+SC effects on commitment to change and self-regulation. Substance use status will be measured using two indicators, percent days abstinent and the urine screen result. *Commitment to Change* will be measured using two indicators at each time point, the Readiness Ruler and the CLEAR change talk score at both baseline and immediate post. Two indicators will also be used to assess *Self-Regulation* at baseline and immediate post: Self-Regulation Questionnaire scores and Balloon Analog Risk Task scores. Additionally, demographic variables will be statistically controlled for in the model (gender, age, race, ethnicity). The MPLUS statistical package[73] will be used for SEMs. To provide a metric for each latent construct and to identify the model, the first construct loading for each latent variable will be set at 1.0. A two-step approach examining the model will be undertaken.[74] First, using confirmatory factor analytic techniques, a test of the proposed measurement model will be conducted and any needed modifications to this model, including testing for measurement invariance over time, will be undertaken prior to examining model fit. The second step involves an examination of the structural portion of the model. The model suggests that BMI effects on substance use are not only direct, but also indirect, mediated by effects on commitment to change and self-regulation. Baseline substance use status, commitment to change, and self-regulation will be controlled for, aiding precision in detecting treatment effects. Fit of the model will be assessed using a chi-square statistic, as well as the more approximate fit indices of the root mean square error of approximation (RMSEA),[75] the comparative fit index (CFI)[76] and the standardized root mean square residual (SRMR) Using various cutoffs for fit assessment helps to minimize Type I and Type II errors.[77] Recommendations that adequate fitting models have *CFI* > .95, *RMSEA* < .06, and *SRMR* < .08 will be adopted here. BMI indirect effects on 6 month substance use will be tested using the bias-corrected confidence limits.[78] Significance will be assessed by whether or not the 95% confidence limits contain zero. The bias corrected approach has been shown to provide the most accurate confidence limits and greatest statistical power when compared with other existing approaches for detecting mediation.[78] Multi-group structural equation modeling will be used to test moderated mediation. Two groups (high vs. low/moderate on affective psychopathy) will be compared. We will isolate differences across models by first examining if measurement parameters are equal across groups. Model differences across groups will be tested using the chi-square difference test. Next, we will test for structural differences across groups, examining regression parameter estimates for equality, followed by an examination of latent variables' variances and means across the groups. Such moderated-mediation will allow for isolation of BMI effects on latent variable means, controlling for process differences across the groups. Four exploratory analyses will also be conducted. The first will examine longitudinal change in substance abuse using growth curve analyses. Substance use is measured at baseline, 4 times during the intervention period, and at 6-month follow-up (6 time points). Time will be modeled so that the intercept reflects baseline status and subsequent time points will be modeled as weeks from baseline. Both linear and curvilinear (quadratic) change

will be examined using the same covariates as previously mentioned. Here, we are interested in the time by condition interaction term, addressing whether the trajectory of substance use differs across the BMI+SC and SC groups. Second, we will determine whether BMI+SC had an effect on violent recidivism using logistic regression. We will also use the structural equation models above to examine mediational and moderated mediation effects of BMI on violent recidivism. Finally, we will also examine the moderated mediation models across gender and race (white vs. black) to determine if mean and/or process differences exist for males and females as well as for White and Black participants. (Numbers of other races/ethnicities are likely to be too low for separate analysis).

D.7.1 Power, Missing Data, and Type 1 Error Protection. For analyses involving continuous mean differences Optimal Design software was used to assess statistical power. With a sample size of 416, we are adequately powered (> .80) to detect a small standardized effect with baseline covariates explaining 40% of the outcome variance (n required = 265 to achieve .80 power). Should baseline covariates explain only 30% of the variance, we are powered at .78 to detect small effects. The inclusion of baseline covariates typically improves precision (at the cost of degrees of freedom)[79] For the logistic analyses predicting urine screen substance use results and 12-month recidivism, power analyses were conducted using the Stata statistical software program. We are interested in the power of treatment status to significantly detect a difference in positive urine screens and violent recidivism by 12 months. In a likely scenario of 50% positive urine screens, we are adequately powered (.80) to detect a 14% or more difference in rates. Power improves slightly as the baseline rates drift away from 50%. Typical 12-month violent recidivism rates are 20%. Here, we are adequately powered to detect a 12% point difference in rates, even if average absolute baseline covariate correlation with treatment is .3. For the structural equation model to be tested,[80] our approach allows for the testing of a null hypothesis of not good fit, reversing the role of the null hypothesis in conventional tests of model fit, so that a significant result provides strong support for good fit. With an expected sample size of 416, adequate power (> .95) to reject an hypothesis of close fit (RMSEA > .08) with 94 degrees of freedom (df) given a population RMSEA of .05 was obtained (proposed model including age, gender, 2 race variable = 94 df). Additionally, adequate power (.99) to reject a hypothesis of not-close fit was obtained. Here, if model fit is extremely good (RMSEA < .01), and we test the hypothesis that fit is not close, we have greater than .95 power to reject the null hypothesis that RMSEA > .05 . Even if sample size drops to 300, power for both the hypothesis of close fit and the hypothesis of not close fit remains above .90. As more degrees of freedom are introduced with the addition of multi-group modeling (psychopathy, gender, race), power improves on the above estimates. For analyses examining mean and rate differences, pairwise deletion of missing data will be used, thus retaining all available information. As a form of sensitivity analysis, however, multiple imputation of missing data will be conducted, which has consistently demonstrated less biased parameter estimates than most other approaches to the handling of missing data.[81] To help control for Type 1 error, the Benjamini-Hochberg (BH) method[82] will be used to adjust for the multiple comparisons proposed. The BH method adjusts for multiple comparisons by controlling the false discovery rate instead of family-wise error rate. It is less conservative than the more traditional Bonferonni methods, yet still provides adequate protection against Type 1 error.