

Integrated Alcohol Disorder and PTSD Treatment

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Primary Outcome Analyses.

6.H.3. Primary Outcome Analyses. The first primary aim is to evaluate if I-PE will demonstrate greater reduction in PTSD symptoms than SS at post treatment. The statistical model will be a random intercept regression model with treatment condition (I-PE, SS) and a linear term for time (0, 2 months). The primary test of the treatment conditions will be treatment x time interaction effect. We will also test the extent to which gender moderates treatment effect. The model can be expanded to determine an adjusted intervention effect by including additional covariates(e.g., age, ethnicity). This model provides maximum likelihood (ML) parameter estimates; allowing modeling of the covariance error structure data across assessment points.⁹¹

The second primary aim is to evaluate if I-PE will result in greater percent days abstinent (PDA) from substance use at 5 and 8-month follow-up. The statistical model will be a random intercept regression model with treatment condition (I-PE, SS) and a linear term for time (0, 2, 5, 8 months). The primary test of the treatment conditions will be the treatment x time interaction effect. A quadratic effect of time will also be tested to model potential decaying treatment effects. We will test the moderating effect of gender on the treatment effect by testing a treatment x time x gender interaction term in the model. Additional covariates can also be added to the model to determine an adjusted intervention effect.

The primary outcomes will be tested using an intent-to-treat framework. If the extent of missing data is small and the data appear to be consistent with a missing-at-random model (MAR), then the maximum-likelihood analysis using all randomized cases and the observed data is an appropriate method for handling the missing data. In the MAR model the missingness can be a function of the observed covariates and observed outcomes. The MAR assumption is plausible in treatment situations, even in studies such as substance abuse in adolescents.⁹² The critical element when conducting MAR-based analyses is to include variables related to the missingness in the statistical model.⁹² Potential variables we will measure that may be related to study drop out are group assignment, social and familial support, employment status, and income. As a check on the sensitivity of our conclusions to the assumption that the missing data are MAR we will conduct pattern-mixture modeling, which is appropriate with data that is likely MAR.⁹³ The distinction between ignorable (MAR) and non-ignorable missingness (missing not at random; MNAR) is generally not empirically testable and we acknowledge the possibility that data may be missing not at random. Therefore, we propose to perform MNAR sensitivity analyses using pattern mixture models. With 3 follow-up assessment points there are 9 potential missing data patterns that can emerge. Some patterns will likely have small numbers of cases precluding parameter estimation for these patterns separately. In this case we will apply the Hedeker and Gibbons (1997) approach that combines missing data patterns to estimates model parameters that are conditional on the missingness using a binary variable in the model to denote missing data at one or more time points.