

**A Pragmatic Trial of Brief CBT for Anxiety in VA Primary Care**

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## DATA ANALYSIS PLAN

### Primary aim: Anxiety and Quality of Life differ as a function of bCBT for anxiety vs. EUC

All analyses will be done on an intention-to-treat basis, and participants will be analyzed in the group to which they were randomized. We will first determine whether participants randomized to the two study arms differed on baseline characteristics, age, race, gender, medical or mental health comorbidities, and anxiety. Chi-square tests will be used for categorical variables and t-test for continuous and ordinal variables.

We will examine the normality of the distributions of both primary outcomes and will consider transformations such as the log or the inverse. Because we are using an unequal randomization (see sample size section), it is especially important to test the assumption about the homogeneity of the variance of the residuals across the levels of the independent variables<sup>31</sup>. For analyses of our primary outcomes, we will test the homogeneity assumption before testing for differences between the bCBT and EUC groups. If the assumption of equal variances is violated, we will use statistical tests such as the approximate t-test, which uses individual sample variances instead of the pooled variance. In addition, we will obtain Satterthwaite's approximation of the degrees of freedom. For the regression models, we will test whether the residual variances are equal and, if necessary, we will fit unequal variance models to obtain better estimates of the standard errors of the difference between groups. We will calculate the absolute differences in outcome measures between baseline and 12-month follow-up and the effect sizes of the bCBT group compared with EUC. We will also examine effect sizes for the bCBT group baseline vs. post-treatment and 8-month follow-up.

To compare changes in anxiety symptoms between the two groups over time, we will use a longitudinal, mixed-model analysis containing terms for the intercept, treatment, time, and interaction between time and treatment. In separate analyses, we will compare changes in quality-of-life between the two groups over time using a similar mixed-model approach. The mixed-model analysis will allow us to nest patients by site. Any baseline characteristics found to be significantly different between bCBT and EUC will be included in the model, *as will any differences in mental health service use*. The four time points (baseline, 4-, 8-, and 12-month) will allow us to assess the immediate impact of treatment and the longer-term retention, improvement, or decay in outcomes. The treatment effect will measure differences between the intervention and control groups at baseline, and the time effect will measure whether there was an overall change over time in the outcome. The term of most interest will be the interaction between time and treatment, which will indicate whether there is a difference over time between the two groups. The use of the random-coefficient model will allow us to fit a line for each participant using his/her available data, including participants with missing values, and maximize the power to detect differences.