

Technology Enabled Services to Enhance Depression Care

NCT05406791

Date: 3/29/24

### **Statistical Analysis Plan**

All effectiveness analyses for the primary (PHQ-9) and secondary clinical (GAD-7, suicidal ideation) outcomes will use intention to treat methods. A comparison of population characteristics (race and ethnicity, age, gender, health status, baseline depression and use of other mental health treatments) must be made between patients receiving TES and the control treatment. Should the populations be different, propensity scores will be estimated for the likelihood of receiving TES, and models will adjust for those scores (trimming the data as necessary). After the population comparison and appropriate adjustment, we will compare overall effectiveness, using generalized linear mixed models (GLMM) to determine if there are differences in effectiveness between individuals receiving TES and CT over time. Separate models will be run for PHQ-9 and GAD-7, using participants who meet entry criteria for each (PHQ-9 > or = 10 or GAD-7 > or = 8, respectively). Missing data will be managed through multiple imputation. Additional covariates will also be included to identify any substantive changes in the service, technologies, and/or implementation plan as a result of optimization during the trial. Moderation of TES on effectiveness. Moderation of patient characteristics (race, ethnicity, income, age, sex, health status, substance/alcohol use, or use of other mental health treatments, including pharmacologic) will be analyzed in individual GLM models by estimating a treatment by moderator interaction in predicting end of treatment depression scores adjusting for baseline levels of depression.