Evaluating Technology Enabled Services in Perinatal Depression

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Data Analysis Plan

Effectiveness. Effectiveness analyses will use intention to treat methods. Given potential bias due to the time delay of implementation, a comparison of population characteristics (race and ethnicity, age, gender, health status, mobile phone competence, baseline depression and other mental health treatments) must be made between patients receiving TES and the eTAU. 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 eTAU over time, while accounting for intraclass correlations (ICC) within CMs, and clinics where necessary. 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.

Moderation of TES on effectiveness. We will examine any moderation of the effect of treatment arm on depressive symptoms by race, ethnicity, age, health status, substance/alcohol use, mobile phone competence, or other mental health treatments, in individual GLM models, by estimating a treatment by moderator interaction in predicting end of treatment depression scores adjusting for baseline levels of depression.

Power. Although a pilot study, we provide an estimate of effect that we can detect with a conservative recruitment of 30 participants in eTAU and 45 participants in TES. As power calculations for delayed roll-out trials involve both between period and within period autocorrelations, which would be speculative at this point, we estimated an effect size with an estimated ICC of 0.01 within clinics. With this assumption, we have 80% power to detect an effect size of 0.76 – a difference in PHQ-9 scores between eTAU and TES of 3.8 assuming a SD of 5. Given this trial is embedded in the COMPASS CC program that receives 30-50 referrals per month, we expect this trial will be able to enroll more participants than this conservative estimate, and as this is the calculated effect size for a simpler analysis, we anticipate this to be conservative estimate.