

Evaluation of Text Message Engagement Support of Mindfulness Smartphone Applications

NCT03633682

March 3, 2020

Statistical Analysis Plan (SAP)

All analyses will be conducted based on intention-to-treat. The primary clinical outcomes for this trial are depression (PHQ-9) and anxiety (GAD-7). We will compare PHQ-9 and GAD-7 scores between conditions using mixed-models. For these models we will include condition (engagement support vs. no engagement support) and assigned app (Headspace vs. Stop, Breathe, & Think) as predictors including the condition by assigned app interaction term to determine if the impact of engagement support on depression and anxiety differ across assigned app. Prior to using mixed-models will test for critical assumptions including collinearity, influential data points, and normality and appropriate tests or modifications will be made where appropriate such as non-parametric tests for violations of normality. Independent models will be run for each depression and anxiety. Due to the pilot nature of the current trial, we will not adjust the error rates for these models. All models will include participant characteristics as a covariate including sex, age, and education. We will also use overall satisfaction of the app identified in the usability session as a covariate to determine if usability concerns relate to eventual benefit attained from a mobile app.

Secondary trial outcomes will include measures of use (self-reported) and satisfaction. We will compare these outcomes using three sets of planned contrasts comparing the main effects: engagement support vs. no engagement support, Headspace vs. Stop, Breathe, and Think, and the interaction term. Due to the pilot nature of the current trial and to the use of planned contrasts, we will not adjust the error rates for these contrasts. For other outcome measures we will use mixed methods where appropriate when we have at least 3 time points of data collection and repeated-measures ANOVAs in other circumstances.