Study Title: Evaluation of a Crowd-Powered Web Platform for Depression and Anxiety

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Statistical Design

Primary clinical outcomes for this trial will consist of symptoms of depression and anxiety. We will compare scores on depression and anxiety (DASS) between the conditions using linear mixed-models. Linear mixed-models are robust to missing data as they do not require complete case data (i.e., at every time point); thus, even participants with missing data at some assessments were included in the analysis and results are modeled on the basis of the available data. Missing data was imputed on any scale if less than 25% of the data was missing in which case the missing value was replaced by taking the mean of the non-missing items for that participant for that particular scale.

Models were a priori adjusted for age, gender, race/ethnicity as well as baseline levels of the dependent variables. For these models, we will include diagnostic status as baseline covariates in mixed-effects repeated measures model analysis using continuous measures (symptom change on DASS) as outcome variables. Mixed-models require at least 3 assessment time points and for dichotomous variables measured with telephone assessments at fewer time points we will be evaluated using descriptives, chi-square and t-tests. We will examine mediation using the Preacher and Hayes bootstrapping procedure. This procedure produces the bias-corrected and accelerated bootstrapped confidence intervals of the product of the direct pathways between condition and the mediator (a) and the mediator and the outcome (b) to estimate the indirect effect (ab).

Power

We note that RFA-MH-18-706 supports pilot effectiveness research to evaluate the feasibility, tolerability, acceptability, safety and preliminary indications of effectiveness of interventions; to examine whether the intervention engages the target/mechanism that is presumed to underlie the intervention effects; and to obtain preliminary data needed as a pre-requisite to a larger-scale effectiveness trial designed to definitely test the effectiveness of interventions. As such, we are not fully powered on all outcomes. Based on our proposed sample size of 50 participants in the treatment and control conditions, we calculated the effect sizes that we would be able to detect on the primary outcomes using $\alpha = .05$ and $ß = .80$ between treatment (the ADAPT platform) versus control. At this sample size, alpha-level, and power, we would be able to detect and effect size of $d = .50$ between conditions.

These enrollment targets reflect the minimum targets that we expect and intend to enroll. Given our integration of Mental Health America's Screening-to-Supports (S2S) platform it remains possible that we can recruit a larger number who we might receive partial data on.