Healthy Minds Program (HMP) App Dosage Study

Statistical Design and Power

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Analysis approach

The feasibility and acceptability of the HMP app for individuals with depression and anxiety will be assessed using benchmarks previously recommended for mHealth research (Hermes et al., 2019). The app will be considered acceptable if ≥75% of participants complete the intervention and adhere to treatment for an average of 7- or 3-minutes per day (for the 15- and 5-minute dosage conditions), 6 days per week. A usability score > 70 on the Systems Usability Scale (Bangor et al., 2008) will be considered acceptable. As our study is not designed nor powered for definitive effectiveness analyses, Cohen's (1988) *d* effect sizes will be used to estimate the magnitude of pre-post changes in symptoms of depression and anxiety. The effect of group assignment on practice dosage will be analyzed using analysis of variance (ANOVA) covarying gender. The relationship between practice dosage and changes in depression and anxiety will be assessed using ordinary least squares regression (OLS) models predicting post-treatment symptom levels while controlling for pre-treatment symptoms and gender. Intensive longitudinal data (i.e., ecological momentary assessment data) will be analyzed using dynamic structural equation modeling (DSEM), accounting for the nesting of observations longitudinally within participants. Cross-lagged models will be constructed to evaluate the temporal sequencing between practice time with mood symptoms (depression, anxiety) and candidate mechanisms (decentering, repetitive negative thinking). DSEM will allow both practice dosage and outcomes (symptoms, mechanisms) to be modeled simultaneously (Hamaker et al., 2018). DSEM also allows assessment of between-person variability in cross-lagged relationships that can inform power analysis for future studies as well as provide substantively useful information regarding individual differences in the link between practice dosage, symptoms, and mechanisms.

Power analysis

Power analyses are based on effect sizes from mindfulness-based interventions for individuals with depression and anxiety reflecting (1) pre-post changes in depression and anxiety and (2) association between practice dosage and changes in psychological symptoms. For pre-post changes in depression and anxiety, Goldberg et al. (2018) conducted a meta-analysis of mindfulness-based interventions (MBIs) versus no treatment control conditions in individuals with depression or anxiety and found mean between-group effects in the moderate to large range (*d*s = 0.59 and 0.89, for depression and anxiety, respectively). To our knowledge, no meta-analysis has been conducted evaluating pre-post changes in depression and anxiety within clinical samples using mobile health MBIs. Moderate to large reductions in depression symptoms have been reported in several mobile health MBI studies with depressed samples (*d* = 1.09 in Dimidjian et al., 2014, *d*s = 1.15 to 1.21 in Ly et al., 2014) and large reductions in anxiety have also been reported in anxious samples (*d* = 1.33; Boettcher et al., 2014).

For the association between practice dosage and changes in psychological symptoms, Parsons et al. (2017) conducted a meta-analysis showing a small magnitude correlation (r = .26). Data from a pilot study using the HMP app in a very small sample (n = 10) also showed moderate-to-large reductions in *DASS-21* stress (d = 0.78) and a correlation between practice time and pre-post changes in stress (r = .27); however, small studies provide a poor basis for conducting power analysis (Leon et al., 2011).

Power for between-group differences in dosage based on randomization to dosage conditions can be roughly estimated based on our preliminary feasibility data (n = 85). Participants will be randomized to 15- and 5-minute dosages. Our naturalistic pilot data showed a mean practice time of 3.91 minutes per day (SD = 3.15, range = 0.0 to 12.2). Assuming randomization produces a 3-minute mean difference between groups (e.g., means of 7 and 4 minutes per day, for 15- and 5-minute dosage conditions) and doubles the standard deviation, there would be a between-group effect of d = 0.48.

No appropriate prior study was available to estimate the magnitude of cross-lagged associations between practice dosage with symptoms and candidate mechanisms within a mobile health MBI. Not knowing the degree of heterogeneity in day-to-day practice time and outcome associations, it is currently not possible to estimate power associated with the intensive longitudinal models. The current study will provide data pertaining to precisely these relationships to inform power analysis and sample size estimation for future trials.

Our planned sample size is n = 90 subjects, and with 10% attrition we anticipate complete T1-T2 data for n = 81 participants. We have 80% power to detect a small-to-medium (d = 0.32) pre-post change in depression and/or anxiety. If basing power on the effect sizes indicated above, we have 99% power to detect a large (d = 1.09) pre-post change in depression and/or anxiety. Based on recommended cut-offs for clinically significant change on the *DASS-21* (9.22 and 6.31 points corresponding to ds = 0.83 and 0.72, for depression and anxiety, respectively; Ronk et al., 2013), the study has 99% power to detect clinically significant pre-post changes in depression and anxiety. We have 80% power to detect a correlation of .31 between practice time and pre-post changes in depression and/or anxiety. If basing power on the meta-analytically-derived effect size indicated above (Parsons et al., 2017), we have 67% power to detect a small-to-moderate (r = .26) association. We have 80% power to detect a small-to-moderate (d = 0.45) between-group difference in practice time based on randomization. If basing power on the effect size indicated above, we have 85% power to detect a small-to-moderate (d = 0.48) between-group difference.

Based on these power analyses, the sample size is sufficiently powered to detect pre-post changes in depression and/or anxiety, between-group differences in practice dosage, and perhaps an association

between practice dosage and pre-post changes in depression and/or anxiety. As such, this study is unlikely to provide definitive causal evidence that random assignment to varying practice dosages induces changes in depression and/or anxiety, but it can provide preliminary proof-of-principle and effect size estimates for planning future studies.