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Strategies for Treating Anxiety Research Study

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Statistical Analysis Plan

This single-arm study will examine the preliminary feasibility, acceptability, and clinical outcomes among coach and patient participants. Statistical analyses will be conducted with IBM SPSS version 28. Means and standard deviations (SDs) for primary implementation outcome measures will be calculated as summary statistics for: Acceptability of Intervention Measure (AIM); Feasibility of Intervention Measure (FIM); and Implementation Appropriateness Measure (IAM). Feasibility and acceptability outcomes also include examination and summary of the following: (1) recruitment and retention of patient participants (number completing all study treatment visits as a proportion of those enrolled); (2) external rating of coach fidelity to intervention (proportion of those rated as “satisfactory” or above on fidelity rubric); (3) and summary statistics of patient-rated working alliance (Working Alliance Inventory-short form).

Differences between pre- and post-treatment scores on clinical outcomes will be examined using paired t-tests. Effect sizes will be assessed using Hedge’s g, with 0.2, 0.5, and 0.8 representing small, medium and large effect sizes, respectively. Clinically meaningful changes in the primary outcome will be evaluated with: the Reliable Change Index (Jacobson & Truax, 1992), movement out of the clinical range, and the percent reduction in symptoms. RCI scores reflect the change in scores from baseline to posttreatment, divided by the standard error; therefore, it is a method of roughly estimating how far from zero the change in scores is per participant. RCI scores indicative of clinically significant improvement were greater than or equal to 1.96, or a decrease in score of roughly two standard errors (Jacobson & Truax, 1991).

Primary clinical outcomes include pre- and post-treatment changes anxiety severity (Hamilton Anxiety Rating Scale; HAM-A) and avoidance (Multidimensional Experiential Avoidance Questionnaire; MEAQ). Sustained change in anxiety symptoms on the HAM-A and MEAQ (pre-treatment and follow-up at 12 weeks) will also be examined with paired sample t-tests. Secondary clinical outcome is change between pre- and post-treatment global health status and functioning (World Health Organization's Disability Assessment Schedule 2.0; WHODAS 2.0) as assessed by paired sample t-tests. Additional exploratory analyses will examine pre- to post-treatment change and RCI scores in depressive symptoms (Patient Health Questionnaire; PHQ-9), given the high level of comorbidity between anxiety and depressive symptoms.