Analysis Plan for Telehealth Self-Management for Employed Adults
Randomized Controlled Trial
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E-TIPS Trial

Statistical Analysis

Out of 202 participants, 11 (5.4%) were missing their 12-week Pain Interference Score. Because our analysis plan stipulated that if greater than 5% of the primary outcome was missing, we would consider if there were significant predictors for missing the outcome, we conducted this analysis and found that having multiple diagnoses (chi-squared p-value = 0.038), having a higher baseline Average 7-day Pain Intensity Score (Wilcoxon rank sum p-value = 0.025), baseline Pain Catastrophizing Score (Wilcoxon rank sum p-value = 0.002), and baseline PROMIS Pain Interference Score (Wilcoxon rank sum p-value = 0.017) were all significant in predicting missing data at 12 weeks. We then used Heckman's selectivity models of pattern-mixture models with multiple imputation to account for our missing data. Given that our missingness percentage was on the boundary of our set plan, a standard multiple imputation analysis assuming missingness at random was also considered and was consistent with the Heckman's selectivity model approach. All models were multivariable linear models, adjusted for the randomization stratification characteristics of site (UW or AbilityLab), sex (Male or Female), and baseline severity (Average 7-day Pain Intensity Score < 7), and condition (MS, Spinal Injury, Traumatic Brain Injury, Amputation, or Multiple Diagnoses). To assess if there was a difference from baseline in the Pain Interference Score, the outcome was modeled as the 12-Week Pain Interference Score, controlling for baseline. The outcome of observed Pain Interference Score at week 12, the difference from week 12 to baseline, the percentage difference, and a whether a 10-point decrease was achieved were also analyzed, using two sample t-tests or the Chi-squared test, presented along with means, standard deviations, and standardized mean differences.

The continuous secondary outcomes at week 12 were analyzed similarly, with multiple imputation models to account for missing data, and adjusted for the same set of covariates. P-values were adjusted using a Bonferroni correction. Further follow-up outcomes at month 6

were analyzed using mixed effects models with repeated measures. The outcomes at baseline, week 6, week 12, and month 6 were included, with the same covariates as above included as fixed effects: treatment, time point, treatment by time point interaction, site, sex, baseline severity of pain, and condition. An exponential spatial correlation structure was used as the assessments were not equally timed. Contrasts across treatment and across time points were calculated.