My Surgical Success: A Randomized Controlled Pilot Study of a Pre-surgical Psychological Intervention

Statistical Analysis Plan

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Statistical Analysis

Statistical Analysis All analyses were conducted using SAS9.4. For acceptability and patient-reported outcomes, group differences were tested using analyses of varaiance (ANOVAs) for numerical covariates and chi-square tests for categorical covariates. The effect of the MSS vs HE control on opioid cessation in the 12-week postsurgical follow-up period was assessed using survival analyses. The opioid stop event was considered to have occurred if the patient reported an opioid stop date and was censored otherwise. Duration to opioid cessation was computed as days from surgery to the last patient-reported date of opioid stoppage or last known patient contact (for censored observations). Product-limit survival estimates (Kaplan-Meier curves) and the log-rank test of equality of survival curves between the MSS and HE control groups were generated using PROC LIFETEST. Time to opioid cessation event was assessed using a Cox proportional hazard regression model with the experimental condition as the predictor following a supremum test of the validity of the proportionality assumption (PROC PHREG). Two follow-up analyses were conducted. First, we tested whether MSS and HE control differed in the odds of postsurgical opioid cessation (independent of duration) using a logistic regression model (PROC LOGISTIC). Second, we tested whether the median time to opioid cessation was different between the two groups using a nonparametric test of medians (PROC NPAR1WAY with the median option). For each of the psychological covariates (pain catastrophizing, pain intensity, pain interference, anxiety, depression, and physical function), we assessed the treatment effect (MSS vs HE control) as follows. We first assessed whether there was evidence of a treatment time effect in the postsurgical period (two-, four-, eight-, and 12-week follow-up), and finding none, we averaged the postsurgical measures to create a composite postsurgical measure. For each of the covariates, we then specified a mixed-design ANOVA with treatment (MSS vs HE control, between-subjects), time (pre vs post, within-subjects), and the treatment time interaction as predictors.

Power Analysis The study was designed to detect a hazard ratio of 1.9, the equivalent of a “medium” effect in terms of Cohen’s d [23, 24], for the effect of the MSS treatment vs HE control in the 12-week postsurgical follow-up after surgery using Cox proportional hazards regression (PROC POWER). The analysis indicated that a total sample of 82 patients would be needed to yield a power of 0.8 and a two-tailed alpha of 0.05.