Study Title:

Motivational Interviewing and Guided Opioid Tapering Support to Promote Postoperative Opioid Cessation

NCT03659734

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Analytic Plan: Results of Cox and logistic regression analyses will be reported with and without stratification by gender. The intention-to-treat (ITT) analysis will include all patients with at least one set of follow-up data after randomization. We will examine the distribution of baseline covariates amongst groups to establish adequacy of randomization. We will use Kaplan Meier analysis and the log-rank test of significance to compare the groups at a two-sided a level=0.05, to identify a difference in time to opioid cessation. We will use Cox regression to adjust for potential confounders only if randomization is inadequate, and for surgery type. (Adequate randomization should adjust for confounding. In the event that the baseline covariate distribution amongst the groups are unbalanced, these specific covariates will be tested as potential confounders.) We will evaluate the effect of treatment group on time to opioid cessation. For sensitivity analyses, we will compare models from manual and automated selection techniques through AIC values. We will test for non-violation of the proportional hazards assumption and linearity assumptions of continuous predictors. Secondary outcomes include time to complete opioid cessation.

In a similar ITT analysis, we will compare the proportion of postoperative opioid misuse between groups, using the chi-square test. We will use logistic regression to characterize the effect of group on postoperative opioid misuse, with adjustment for confounders (only if randomization is inadequate) and surgery type. Sensitivity analyses will similarly compare -2 Log L scores of models. We will test linearity assumptions of significant predictors.