

Statistical analysis plan

Title: A clinician training intervention to improve pain-related communication, pain management and opioid prescribing in primary care

NCT Number: NCT03629197

Date: February 9, 2016

For this pilot study, our target sample size of 48 patients was powered to have 80% probability of detecting an intervention effect of 0.78 standard deviations, assuming a two-sided test, $\alpha = 0.05$, clinician-level ICC of 0.1, and a cluster size of 2. Primary outcomes were clinician use of targeted communication behaviors and patients' pain-related interference 2 months after their visit. Secondary outcomes were patients' pain intensity 2 months after their visit, physician self-efficacy for communicating about chronic pain, physician-reported visit difficulty, patient visit experience, and clinician assessment of the intervention (process measure). Additional, exploratory outcomes were change in prescribed opioid dose 2 months after each patient's visit and number of targeted communication behaviors observed for each individual step in the communication framework.

We will first compare baseline patient and physician characteristics for the intervention versus control group by examining the coefficient associated with the arm assignment variable. We will use Poisson regression with robust standard errors to model number of observed communication skills per visit and linear regression for all other outcomes. We will use generalized estimating equation with robust standard errors to account for patients being clustered within clinicians, because this approach is more robust to outlier values in small samples than mixed effects models. For dependent variables that are measured more than once (pain intensity, pain-related interference, clinician self-efficacy, and prescribed opioid dose), we will adjust models for baseline values rather than operationalizing these outcome variables as change from baseline. In addition to arm assignment, primary analyses will be adjusted for clinic (family medicine versus internal medicine) because randomization was stratified by clinic. If measures have substantial unadjusted differences between arms (indicating failure of randomization), we will explore adding them as covariates to multivariable models. Analyses will be conducted using Stata 17.