

Mechanisms of Psychosocial Treatments on Opioid Use in Chronic Pain

Statistical Analysis Plan

Plan Date: July 23, 2024

IRB Title: Mechanisms of Psychosocial Treatments on Opioid Use in Chronic Pain

Short Title: Living in Full Even (LIFE) with Pain Study

NCT Number: NCT03916276

Mechanisms of Psychosocial Treatments on Opioid Use in Chronic Pain

A randomized, 3-group, parallel-design, 90-subject clinical trial to test the mediators and moderators of cognitive therapy, mindfulness meditation, and activation skills on individuals with heterogeneous chronic pain conditions who are at risk for opioid misuse.

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Estimates of treatment effects on outcomes. Descriptive statistics were computed for all outcomes. At each follow-up time (post-treatment, 3- and 6-month follow-ups), the average daily medication in MME was categorized into three groups (increase in dose, decrease in dose, or no change in dose from pre-treatment to follow-up), and then calculated the proportion of individuals at each follow-up time that increased dose, decreased dose, or reported no change. We also calculated the 95% confidence interval (CI) for those proportions using Jeffreys method (Bayesian). We then compared these proportions between treatment conditions using a Chi-square test. We also calculated the difference in proportions (and 95% CI's) between each pair of interventions.

We calculated the mean and standard deviation of the change from pre-treatment to follow-up of all of the secondary outcomes, as well as their effect sizes (Cohen's d's) and 95% CI. We compared the mean changes of the interventions via an ANOVA (change in outcome as response and intervention group as a factor), and calculated between groups effects and 95% CI. Effect sizes were calculated using the macro effect size in R software.