Computer Based Treatment for Cognitive Behavioral Therapy and Cooperative Pain Education and Self-Management --CBT4CBT-COPES

Clinicaltrials.gov ID Number : NCT 05204576

Statistical Analysis Plan

HIC Protocol 20000 26276

APPROVED BY THE YALE UNIVERSITY IRB 7/19/2024

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Data analyses and power
Effect size estimates for CBT4CBT-COPES on retention come from our previous CBT4CBT research indicating a small to medium effect size for treatment adherence (*delta* .23 to .42) and opioid outcomes (*delta* .40)69. Our non-inferiority trial of COPES compared to clinician delivered CBT for primary chronic pain found no significant differences in pain outcomes by treatment (clinician CBT versus COPES), allowing us to infer effect sizes consistent with previous metaanalyses51. We used G*Power and estimated that for the primary endpoint analysis, with a sample size of 160 (80/group), power would be adequate (>.80) to detect a 20% difference in adherence, consistent with a small to medium effect. As a Stage 1 trial, a conservative estimate of a small to medium effect improves our chances of finding differences when they exist.

Specific Aim 1: Primary Hypothesis 1a. CBT4CBT-COPES, compared to standard treatment as usual (TAU), will improve OAT adherence at the 3-month point. The principal strategy will be logistic regression assessing retention defined by dichotomous continuous enrollment in agonist treatment, with evidence of agonist treatment adherence in the week prior to day 84, with OAT type as a covariate.

Secondary Hypothesis 1b. CBT4CBT-COPES will be associated with greater reductions in pain interference than TAU at the 3-month point. Changes in pretreatment to post treatment pain interference will be evaluated with a MANOVA assessing the 2 PROMIS Pain Interference Short Form scores by treatment condition with OAT type as a covariate.

Specific Aim 2: Primary Hypothesis 1a. CBT4CBT-COPES, compared to TAU, will have durable effects at 6-month follow-up (9 months post randomization). The principal strategy will mirror the post treatment analyses with logistic regression assessing adherence rates and MANOVAs evaluating PROMIS pain interference score change from baseline to follow-up.