A Feasibility Study: Understanding and Altering Pain Expectations in Subjects With
Osteoarthritis of the Knee or Hip
Statistical Analyses Plan

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To address the two primary hypotheses, linear mixed effects models will be employed. For each model, subject will be specified as a random effect to account for the repeated measures within individuals. To examine the impact of drug (i.e., placebo, gabapentin, modafanil) on tonic pupil diameter, pupil diameter will be regressed on fixed effects for drug, time (i.e., pre-drug vs post-drug), and a drug x time interaction. A group x time integration would be interpreted as evidence supporting the hypothesis that drug differentially impacted baseline pupil over time.

To examine the impact of tonic pupil diameter on the relationship between cognitive style (i.e., catastrophizing-optimism dimension) and pain reporting, VAS scores will be regressed on fixed effects for catastrophizing-optimism, tonic pupil diameter, and the interaction between catastrophizing-optimism x pupil diameter. A statistically significant interaction would be interpreted as evidence that tonic pupil diameter moderated the relationship between cognitive style and pain reporting. Where appropriate, all analyses are two-tailed with statistical significance interpreted at $p < 0.05$. The analyses will be conducted using R 3.4 and R Studio.

The sample size was based on estimating the feasibility of the protocol and on establishing effect size estimates. No formal statistical power calculations were conducted.