



Biomedical Development Corporation

Cover Sheet

Title: mHealth for Patient Self-Management of Opioid Use Disorder

NCT#: NCT03633929

Unique Protocol ID: 2018-1-100-OUD

Document Date: May 14, 2020

Statistical Plan

Mean, median, and standard deviation were calculated for usage, SUS and patient questionnaire data. Paired-sample student's t-tests were conducted to determine differences in pre-post mean scores for: 1) WHOQOL domain scores and individual questions; and 2) PHQ-9 total score and individual questions.

Scores for each variable entered into KIOS by study subjects were averaged over each week for each participant to account for their having different numbers of assessments. Calculations were similarly made for an overall KIOS Index score (sum of all variables except *Craving*) and for Emotional (*Depressed Mood, Anxiety and Irritability*), Physical (*Pain, Agitation/Restlessness, Difficulty Sleeping*) and Social (*Absenteeism, Difficulty with Usual Activities, and Conflicts with Others*) subgroups. Changes in mean values for each week were calculated relative to baseline measures and student's t-tests were conducted for significance between baseline and the weekly means. Chi-square tests were performed on subject-reported Exercise, Good Sleep Habits and Avoidance of Triggers and High-risk Situations.