Virtual Empowered Relief for People With Chronic Pain Who Take Methadone or Buprenorphine

Statistical Analysis Plan

NCT05057988

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Statistical Analysis Plan

Primary Outcome Analysis to Determine Feasibility

To determine the feasibility of a future RCT, we will evaluate the following criteria.

1. At least 75% of enrolled participants will attend the web-based ER class.
2. Demographic data (sex, age, race or ethnicity, education, income) will be compared between those who drop out and complete the study at the primary end point.
3. The mean scores of the 3 primary feasibility outcome measures will meet or exceed an 80% threshold of acceptability (8 or higher on a 0-10 scale).
4. The qualitative interview data will be analyzed to evaluate perceived feasibility and to identify areas for improvement in the study design for a future, large-scale RCT.

Secondary and Tertiary Outcome Analysis to Examine the Preliminary Efficacy

To test the secondary and tertiary hypotheses, repeated-measures ANOVAs will be conducted to examine whether the secondary and tertiary outcomes will be significantly changed over time. False discovery rate adjustments will be used to control for type 1 error for the multiple comparisons. If the ANOVA results reveal significant change in the outcomes over time, post hoc analyses will be conducted to examine whether the secondary and tertiary outcomes will be improved by 1 month (primary end point) or 3 months (secondary end point) after the web-based ER class.