STATISTICAL ANALYSIS PLAN

Official Title: Treatment Engagement in Families with Substance Use and Psychosis: A Pilot Study

NCT #: NCT05380583

Date: 02/06/2025

Outcome Measures

Primary Outcome Measure:

Outcome 1

Title: Family Wellbeing: Depression

Description: Beck Depression Inventory-II total; scores range from 0 to 63 with higher scores representing more severe depressive symptoms.

Time Frame: Baseline, mid-intervention (week 4), post-intervention (week 8)

Secondary Outcome Measures:

Outcome 2

Title: Family Wellbeing: Anxiety

Description: State-Trait Anxiety Inventory-Short Form; total scores range from 6 to 24 with higher scores representing more severe anxiety symptoms.

Time Frame: Baseline, mid-intervention (week 4), post-intervention (week 8)

Outcome 3

Title: Family Wellbeing: Relationship

Description: General Happiness item on Relationship Happiness Scale; scores range from 1 to 10 with higher scores representing greater relationship happiness.

Time Frame: Baseline, mid-intervention (week 4), post-intervention (week 8)

Outcome measures. The **primary outcome** is 1) family member depression on the BDI-II. The **secondary outcomes** are 1) family member anxiety on the STAI-SF (6-item state measure), and 2) family member-identified patient relationship quality with the general happiness item on the Relationship Happiness Scale. The remaining outcomes are exploratory including family member reported identified patient outcomes (e.g., readiness to change substance use, % past 30-day substance use, and % past 30-day treatment session attendance)**.**

Data Analysis. The **primary statistical model** for the mean of the outcome variable includes terms for treatment, time, and the treatment-by-time interaction. The **primary measure of effect** is the treatment-by-time interaction term for the post 8-week outcome. To adjust standard errors for the correlation of observations, we will use generalized estimating equations.

Procedure for Testing Primary and Secondary Outcomes. To control for the effects of multiple comparisons, we will first perform a test of the primary outcome. If the primary measure of effect achieves statistical significance (defined as $P < 0.05$, 2-tailed), then the two secondary outcomes will be evaluated with statistical testing. If the primary measure of effect fails to achieve statistical significance, then the secondary outcomes will be analyzed descriptively (e.g., calculating confidence intervals without P values).