Official title: A Community-Clinic Collaboration to Improve Outcomes in HIV+ Substance Users Released from Jail

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Outcomes and Data Analysis Plan. The primary outcomes of this pilot study are HIV viral load and substance use at 6 months. We will continue to follow participants until 12 months to examine sustainability of this intervention. We have specifically chosen a pragmatic randomized controlled trial design as it will provide robust results and yet be anchored in a real-world jail setting, increasing its scalability to other sites.

Primary Outcomes*.* HIV viral load is the primary HIV-specific clinical outcome due to its rigor as a biologic result which: a) reflects adherence to HIV medications, b) predicts individual clinical outcomes and c) is associated with HIV transmission risk. This outcome will be analyzed as proportion of individuals who have achieved an undetectable viral load (<200 copies/mL) at 6 months after randomization, and this result will be compared between the two randomized groups using a two-sample proportions test. Secondary analyses will use t-tests to compare absolute differences in HIV viral load.

The primary substance use outcome will be the ASSIST score for the patient's main drug of choice and operationalized as the change in ASSIST score at 6 months from baseline. The ASSIST is a validated measure of substance use in incarcerated populations, has strong psychometric properties, and is easy to administer and score. The ASSIST was chosen because it is a rigorous and relevant measure for this study population as it assesses lifetime use, use in the past 3 months, health, social, legal, and financial problems frequency; interference with responsibilities and lack of control over use.

Established ASSIST scoring methods will be used to calculate a substance involvement score for each class of substance (range 0-39, tobacco range 0-31), resulting in 10 scores per participant. The primary substance use analyses will compare change in the continuous ASSIST score (6 months minus baseline for main drug of choice) in each arm using a t-test. Secondary analyses will use a similar approach to assess differences in the non-main drug of choice ASSIST scores by study arm. Urine drug screen results obtained at 6 months will evaluate drug use in the days just prior to the visit. We will analyze this as a binary outcome (positive v. negative for main drug of choice) using a chi-square test. Secondary analyses will use a similar approach to assess differences in the remaining (non-main) drugs that were tested via urine drug screen.

Secondary outcomes. A key secondary outcome is recidivism and we will collect and compare mortality and causes of death between the two groups. We will employ appropriate comparisons for binary variables (recidivism), count variables (mortality), though we are not powered to compare these secondary outcomes statistically in this pilot RCT, and these will be used for generating hypotheses.