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Buprenorphine to Improve HIV Care Engagement and Outcomes (BRAVO) Randomized Trial: Baseline analysis protocol by C. King (P. Korthuis team)

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Protocol status: Working
This protocol is ready for use in analysis

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Troubleshooting

Overview

1 This protocol is for data analysis as part of the **Buprenorphine to Improve HIV Care Engagement and Outcomes (BRAVO) Randomized Trial**. The BRAVO trial enrolled patients with HIV and moderate-to-severe opiate use disorder to receive either methadone maintenance therapy (MMT) or buprenorphine/naloxone (BUP/NX) at six Vietnamese HIV clinical research sites between 2015 and 2019.

Study Outcome

2 The **study outcome** is HIV suppression at time of enrollment, quantified as less than 200 copies of HIV-1 RNA virus in lab testing.

Covariates

3 **Binary and categorical covariates** included gender (male/female), greater than 9th grade education (yes/no), currently employed (yes/no), currently married (yes/no), currently on ART (yes/no), Hep B positive (yes/no), Hep C antibody positive (yes/no), positive tuberculosis screen (yes/no), history of 06 rehabilitation (yes/no), and other drug use (methamphetamine or amphetamines/methadone/buprenorphine/daily tobacco use/heavy alcohol use/none). Heavy alcohol use will be defined using the AUDIT score.

Continuous covariates include mean age and years since HIV diagnosis at the time of diagnosis.

Age will be reclassified into 10-year categories during covariate testing to increase usefulness in study results.

Data Analysis

4 **Primary Analysis**
Two logistical regression models (univariate + age and sex, and univariate + all covariates) will be built to model the relationship of baseline participant characteristics with the binary variable for HIV suppression (HIV-1 RNA < 200 copies/mL).

5 **Model Fitting**
We will fit the logistic regression using an estimated covariate ratio of 10 events per degree of freedom.
All continuous covariates will be evaluated for linearity in the log-odds using Lowess scatter plot (comparing HIV suppression and each continuous covariate, individually).
Covariates will be examined for multi-collinearity. If covariates are colinear (p>0.80), the research team has decided to include covariates with more variability among

participants; where variability is similar, the research team will consult the clinical team for guidance.

6 **Missing Data**
Missing HIV viral load at baseline will be imputed as “not suppressed”. We anticipate minimal missingness in baseline data among covariates, and will analyze this data using complete case analysis.

7 **Model testing**
We will carry out Hosmer-Lemeshow tests for regression models to ensure the models are well-fit, using an alpha level of 0.05.

8 **Sensitivity analysis**
One sensitivity analysis for the regression model will be conducted. Influential observations will be identified using Pregibon’s Delta-Beta statistic; observations with a Delta-Beta statistic greater than 0.20 were removed. Significant sensitivity analysis results will be reported alongside primary analysis results.

Technology

9 All data will be analyzed using Stata IC Version 15.