# HIV and Alcohol Research center focused on Polypharmacy (HARP) Pilot 1

**ClinicalTrials.gov ID** NCT05560932

**Sponsor** Yale University

**Information provided by** Yale University (Responsible Party)

## Statistical Analysis Plan

Approved May 14,2025

| Variable | Assessment tool |
|---|---|
| **Primary outcome measures** | |
| Feasibility | • Evaluation of recruitment capability and resulting sample characteristics<br>• Evaluation and refinement of data collection procedures and outcome measures<br>• Evaluation of resources and ability to manage and implement the study and intervention |
| Acceptability | Responses to the following questions from the post-intervention surveys (immediately post-intervention; 30 days after the booster):<br>• How comfortable were you with the way that the information about the number of medications that you take was presented? (Somewhat or very comfortable)<br>• How helpful did you find the information about your medications? (Somewhat or very helpful)<br>• How comfortable were you with the way that the information about your PEth score was presented? (Somewhat or very comfortable)<br>• How helpful did you find the information about PEth? (Somewhat or very helpful)<br>• Having a pharmacist (versus another type of provider) talk with me about these issues was very unhelpful, somewhat unhelpful, neither unhelpful nor helpful, somewhat helpful, strongly helpful? (Somewhat or strongly helpful)<br>• The length of the visit was much too long, a little too long, about right, a little too short, much too short? (about right)<br>• Qualitative questions |
| **Exploratory outcome (efficacy) measures** | |
| Alcohol consumption | Determined by comparing pre- and post-intervention readiness to change metrics. Behavior change will be assessed using changes in:<br>• PEth values (primary outcome) (collected at baseline [pre-intervention], and 30 days after the booster)<br>• Self-reported AUDIT-C[30] (baseline [pre-intervention], immediately after the booster, and 30 days after the booster) |
| Medication count | Assessed by medication reconciliation at baseline and at the booster call |
| Bothersome symptoms | HIV Symptom Index[33] (collected at baseline, immediately post-intervention, 30 days post-intervention) |

### *Analysis*

Descriptive statistics were used to characterize the study participants, to present feasibility and acceptability data, and to describe secondary outcomes. Differences between different timepoints were analyzed using paired t-tests, Wilcoxon Rank Sum, and $\chi 2$ tests, as appropriate for continuous or categorical data. The sample size estimates for our goal of 50 participants were previously described in our protocol paper (Womack et al., 2025. The Feasibility and Acceptability of a Clinical Pharmacist-delivered Intervention to Reduce Bothersome Health Symptoms from Polypharmacy and Alcohol Use and Communicate Risk among People with HIV: Pilot Study Protocol. AIDS and Behavior. 29(2) 482-496). All statistical analyses were performed using Stata Intercooled 13 (StataCorp, College Station, TX).