

Understanding and Intervening With Heavy Drinking Among Patients With HIV and HCV

ClinicalTrials.gov identifier: NCT03652675

Analysis Plan excerpt copied from K23 grant proposal finalized May 6, 2014

12.3.2.13. Pilot study: Primary analyses. Chi-squared analyses will assess differences between conditions in gender, ethnicity, age (dichotomized by median split), and education (dichotomized by high school graduation status). If any demographics differ, they will be controlled; otherwise no variables will be controlled. The primary outcome will be drinking quantity (mean drinks per drinking day in the last month), consistent with previous studies of HealthCall^{15,64,92}. Other drinking outcomes (drinking frequency, maximum quantity, frequency of binge drinking) will also be evaluated. I will determine if drinking decreases differentially between the two conditions using mixed effect GLMs, specifying any non-normal (e.g. Poisson) distributions of the outcomes as needed. Power. The sample size (n=45; assuming 75% retention¹⁵) is adequate for detecting large differences (d=0.85) with 80% power. However, as moderate effects were previously found for MI+HealthCall [d=0.44]¹⁵, a moderate effect *even if not significant* would indicate promise for a full trial.

12.3.2.14. Pilot study: Secondary analyses. Interactions. Because previous work found MI+HealthCall to be particularly effective with alcohol dependent patients¹⁵, the sample will be dichotomized by alcohol dependence (AD; DSM-IV)¹¹⁶, and alcohol use disorder (AUD; DSM-5)¹¹⁵ status. To determine if efficacy differs by AD or AUD, I will conduct GLMs for 60-day drinking quantity, with condition, AD or AUD, and their interaction as predictors. Based on previous work at this clinic, ~50% of patients will have AD, with AUD prevalence higher, given the lower threshold. Interactions with gender and ethnicity will also be explored. Changes in readiness to change and self-efficacy. I will assess differential group change in readiness to change and self-efficacy using mixed effect GLMs. Power. I will be able to detect large interaction effects (f=0.52) and large group differences in self-efficacy and readiness to change (d=0.85) with 80% power.