

## Statistical Analysis Plan

Native-Changing High-risk Alcohol Use and Increasing Contraception Effectiveness Study

NCT03930342

Document Date: 12/22/2024

The primary outcome for this randomized controlled trial was AEP risk over 6 months of follow-up. This outcome was defined as a binary (yes/no) indicator of either risky drinking, ineffective contraception use, or both. AEP risk was ascertained over three-month periods at both three- and six-month follow-ups. We estimated the intention-to-treat (ITT) effect of the intervention on AEP risk from 0 to 3 months of follow-up, 3 to 6 months of follow-up, and, as our primary outcome, any AEP risk from 0 to 6 months of follow-up. The ITT effects were estimated as crude ratios of AEP risk in the Native CHOICES arm relative to the control arm and 95% CIs. These effects were estimated as marginal effects from logistic regression models with AEP risk as the outcome and intervention arm as the exposure. In addition to unadjusted analyses, we also conducted analyses that accounted for pregnancy during the study. For AEP risk and contraception use, pregnancy was considered ineffective contraception, and the outcomes were coded accordingly regardless of participant response to questions about contraception use. Models for risky drinking included pregnancy as a covariate.