

Protocol

Alcohol Metabolism and Disease Risk in Asians

NCT number NCT04967599

Document Date 08/08/2024

Protocol

This exploratory/developmental pilot study uses a parallel study design with a brief online behavioral intervention component. Participants are 360 college students of Asian heritage recruited as two cohorts, a group of incoming first year college students and a group of college students already on campus who report having flushed when they first started drinking alcohol. After a baseline assessment including surveys and DNA collection for genotyping, participants are randomized in equal numbers into one of three feedback groups (n = 120 per group) based on lifetime drinking (Incoming cohort only) and having an ALDH2*2 allele: 1) Phenotype only (PHEN): this intervention provides information on health-related risk associated with alcohol consumption and alcohol metabolism gene variations plus personalized feedback on flushing phenotype and associated risks; 2) Phenotype and Genotype (PHEN+GENE): the PHEN intervention plus personalized feedback on alcohol metabolism genotypes and associated health-related risks; or 3) CONTROL: an attention control session that does not provide feedback included in PHEN or GENE. Participants then are followed in four post-intervention behavioral surveys over 10 months and in the final 10-month follow-up also complete an evaluation of the study and retention of the intervention information. Our alcohol outcome measures include peak quantity (primary) and secondary measures of drinking frequency, weekend drinking, and total amount of drinking. Additional secondary outcome behaviors include percent of time used flush cures when drinking and transition to drinking in initial non-drinkers.

Data Analysis Plan

Alcohol Metabolism and Disease Risk in Asians

NCT number NCT04967599

Document Date 08/08/2024

Data Analysis Plan

We conduct nonparametric group comparisons to test for group differences among the three intervention groups in our primary and secondary outcomes. For outcomes that are continuous (alcohol consumption measures), we conduct the Kruskal-Wallis test. For the non-drinker and the flush cure use outcomes that are categorical, we conduct either the uncorrected chi-squared test when all of the expected cell counts are at least 5, or the Fisher's exact test when any of the expected cell count is less than 5. We adjust the p-value for significance to a more conservative value of $<.01$ to adjust for multiple comparisons.