

PROTOCOL TITLE:

Alcohol and Violence Prevention for College Students

PRINCIPAL INVESTIGATOR:

Amanda K. Gilmore, PhD

Sample Size and Analyses

Sample size for the randomized pilot trial was determined, using PASS®, to estimate the variability within a reasonable margin of error. This calculation also accounted for the low base rates of SA and 20% attrition. To estimate variability using a 95% two-sided confidence interval, within a margin of error of 80%, 53 total participants are needed. (For example, if the standard deviation is 10, the confidence limits would be 7 to 15. To design a future trial if we wanted to be conservative, we will use a standard deviation of 15.) We further adjusted the sample size considering low base rate and attrition. SA victimization is a low base-rate experience with a total of 60% of college women who engaged in HED reporting at least one SA victimization experience within a 3-month follow-up period¹². To account for this low base-rate experience, a total of 132 participants are needed. Preliminary studies by the research team estimate that there will be 20% attrition over a 3-month follow-up period, therefore, the final sample size for this pilot study will be 162 (n = 54 per risk group) to account for attrition rates.

We will perform secondary analyses using linear mixed model ANOVAs to determine the factors that potentially predict outcomes including alcohol use, SA victimization, and bystander intervention.