

Project Title: Assessing the Feasibility of a New Prevention to Reduce Alcohol-related Sexual Revictimization of College Women

NCT#: NCT05257603

Document Date: 07/02/2018

Statistical Design and Power

Data Analyses

For the RCT, data will be analyzed according to the intention-to-treat principle [122]. All participants who complete the baseline assessment will be followed (i.e., post-intervention, 3-month and 6-month post-intervention) regardless of treatment participation. Given our experience and past record of retaining participants in longitudinal studies and the relatively brief period of follow-up (6-mos), dropout due to attrition is expected to be low. We anticipate no more than 5% of data will be missing through attrition or wave nonresponse (i.e., not completing all measures at a given time period). To adjust for any missing assessments, we will use multiple imputation procedures [123, 124].

We have three specific hypotheses for the RCT, our analyses are organized below for each hypothesis.

Hypothesis a: Participants in the RPCW intervention will report fewer days of hazardous drinking and improved perception of SRV risk cues on the video risk perception measure (primary outcomes) as compared with participants in the HEC condition.

Differences in relevant outcome variables (e.g., number of heavy drinking days, perception of SRV risk cues) will be tested using a 2 (Condition: RPCW vs. HEC) x 4 (Time: baseline, post-treatment, and 3- and 6-month post-treatment) repeated-measures analysis of variance (RM-ANOVA). The primary effects of interest are the intervention condition main effect and the intervention x time interaction. If a significant condition by time interaction is found, it means that (a) change over time in heavy drinking days differs across intervention conditions and (b) the effect of intervention condition on the outcome is different across time. Therefore, a significant intervention condition by time interaction will be explored by computing the conditional effect of time for each intervention condition and (b) the conditional effect of treatment condition at each of the four time points.

Hypothesis b: Participants in the RPCW intervention will report increased knowledge of safe dating practices and protective behavioral (drinking) strategies (secondary outcomes) compared with participants in the HEC condition.

Differences in relevant outcome variables (e.g., safe dating practices, protective behavioral drinking strategies) will be tested using the same 2 (Condition) x 4 (Time) repeated-measures analysis of variance (RM-ANOVA) described above for hypothesis a.

Hypothesis c: Participants in the RPCW intervention will report lower rates of SRV as compared with participants in the HEC condition at 6-month post-intervention follow-up.

Given that SRV has a low base rate of occurrence, we consider this hypothesis exploratory and will conduct a preliminary comparison of the incidence of SRV at 3-months and 6-months post-treatment across the RPCW and HEC conditions using a chi-square test.

Effect sizes will be calculated with all analyses in preparation for a Stage II efficacy trial of the intervention.

Power

The sample size of 96 women (48 women per intervention condition) was selected to provide 80% power to detect at least medium effect sizes in RM-ANOVA. For **Hypotheses a and b**, power calculations were conducted for a 2 (treatment condition) x 4 (time) RM-ANOVA. We calculated power using the following assumptions (1) a sample size of 48 women in each intervention condition (RPCW, HEC), (2) 4 time points for assessment (baseline, post-intervention, and 3- and 6-months post-intervention), (3) a range of correlation values among repeated assessments ($r = .3$ to $.9$), (4) no violation of the sphericity assumption, (5) $\alpha = .05$, two-tailed, and (6) power = 80%. Based on these assumptions, there is 80% power to detect an intervention condition main effect with medium effect sizes ($f = .20$ to $.28$) and both a time main effect and an intervention condition x time interaction with small to medium effect sizes ($f = .05$ to $.21$). For **Hypothesis c**, statistical power was estimated for a χ^2 test (1 df) of the number of women who were and were not revictimized post-treatment by intervention condition (RPCW, HEC). Assuming (1) a total sample of 96 women, (2) $\alpha = .05$, and (3) 80% power, the chi-square analysis can detect a medium effect ($w = .29$) at 3- and 6-month post-intervention.