Statistical Analysis Plan

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Study Title: *PNF 2.0: A Novel, Gamified, Facebook-Integrated PNF Intervention to Reduce Alcohol Use and Negative Consequences among Sexual Minority Women*

Trial Registration: ClinicalTrials.gov NCT03884478;

https://clinicaltrials.gov/ct2/show/NCT03884478

Data Analysis Plan

Analysis of Intervention Efficacy & Feasibility

An intent-to-treat approach will be used to examine LezParlay treatment PNF effects at 2 and 4 months postintervention on 3 outcomes: estimated number of drinks per week, peak number of drinks on 1 occasion, and number of negative alcohol-related consequences. Preliminary analyses will examine potential biases related to attrition and missing data, inspect outcome distributions, and evaluate potential baseline differences among conditions. As the latter 3 outcomes are count variables (ie, estimated drinks per week, peak drinks, and negative consequences), they may be skewed and best approximated by either Poisson or negative binomial distributions.

Analytic Plan for Evaluating Efficacy

Main effects. At 2 and 4 months after the delivery of treatment PNF, participants in both conditions receiving treatment PNF on alcohol use (ie, alcohol+coping and alcohol only) are expected to report reduced drinks per week, peak drinks, and negative consequences relative to those in the control PNF condition. Furthermore, participants in the alcohol+coping condition are expected to exhibit larger reductions in their alcohol use and negative consequences at postintervention follow-ups than participants in the alcohol-only PNF condition. Multilevel models (MLMs) with full maximum likelihood specification will be used to test these predictions. Time will be specified as a level 1 varying predictor nested within individuals (level 2). Intercept treatment differences will represent treatment differences at baseline (eg, conditional differences in drinking at baseline), and slope differences will represent changes over time (eg, did participants in treatment conditions reduce their drinking between baseline and follow-up assessments more than control participants). The intercept includes a random effect, which will model the subject-specific heterogeneity in alcohol-related outcomes, thereby controlling for correlated data due to individuals. Main effect models will also control for covariates: age, sexual identity, race, ethnicity, relationship status, and severe interpersonal stigma exposure. Significant time*condition interactions will be decomposed via post-hoc Tukey tests.

Tests of Mediation & Moderation. Tests of mediation will examine whether perceived drinking norms at the 2-month follow-up mediate relationships between condition and alcohol-use outcomes at the 4-month follow-up. Mediation will be tested via one of two methods depending on variable distributions and consistency of main effects across outcomes. In the event consistency is not high, an SEM framework will be utilized to examine whether individual norm variables at the 2 month follow-up explain the relationship between PNF condition and the corresponding outcomes at the 4 month follow-up. Alcohol use outcomes at the 4 month follow-up (weekly drinks, peak drinks and consequences) regressed onto the mediator variables, drinking norms at the 2 month follow-up (perceived LBQ weekly drinks, peak drinks and consequences; β_{1-3} paths); drinking norms at the 2 month follow-up will be regressed onto Alcohol PNF and Alcohol+Coping PNF (α_{1-6} paths) and baseline drinking and norms (baseline covariates); and drinking outcomes at the 4 month follow-up will also be regressed onto Alcohol PNF and Alcohol+Coping PNF (c paths) and baseline drinking and norms. Intervention conditions will be dummy coded, and the Control PNF will be excluded from the model (reference group). The joint significance test will be used to determine whether mediation effects are significant. Bootstrapping (N=2000) will be conducted to address non-normality typically associated with drinking outcomes. Thus, direct and indirect effects in the model will be

considered non-significant (p > .05) if the asymmetrical 95% confidence intervals (CIs) include zero and significant (p < .05) if they do not include zero. Alternatively, in the event that main effects are highly consistent across outcomes, mediation will be tested more simply using PROCESS bootstrap tests (N=2000) featuring composite variables for alcohol-related outcomes (composed of weekly drinks, peak drinks, and consequences) and alcohol-related normative mediators (composed of perceived norms for weekly drinks, peak drinks, and consequences).

Tests of moderation will be examined within an MLM framework and will examine whether the efficacy of treatment PNF varied as a function of participants' baseline drinking, sexual identity, exposure to severe interpersonal stigma, or other demographic characteristics (i.e., age, racial/ethnicity, relationship/marital status). In the presence of significant interactions, exploratory moderated mediation models may be conducted using PROCESS software to simultaneously estimate the conditional direct and indirect effects associated with the different levels of moderating variables.

Power Analysis. Informed by previous research examining the effects of web-based alcohol PNF on changes in normative perceptions and drinking in other populations at a 1-2 month follow-up (Cohen d=0.22), the comparably larger effect size revealed in a similar gamified PNF intervention for college students (Cohen d=0.46), power analyses using the standard 0.80 power of detecting a significant effect, *p* < .05, and an effect size of Cohen d=0.30 indicate a sample size of 375 (125 participants in each condition) to be sufficient to detect small-to-medium effects using repeated measures MLMs (ie, 2 levels, 3 arms, and randomization at the individual level) as well as tests of mediation and moderation. Thus, our sample size of 500 will allow us to detect modest effects with even 30% attrition

Data Analytic Plan for Evaluating Feasibility
Descriptive statistics will allow us to assess SMW's level of interest in the LezParlay competition and engagement with the app (i.e., total number of sign-ups and average number of log-ins), recruitment origins (e.g., HER app ad, Facebook, Instagram, and player referral), acceptability (mean rating overall and by competition component), and perceived benefits (i.e., proportion of evaluation study participants who reported benefits). Qualitative text entry responses to items assessing the perceived benefits of the LezParlay competition and improvements or features requested for the next version will also be coded by theme or category using a generic inductive qualitative coding approach.