ClinicalTrials.gov Data Entry Cover Sheet

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Project Title: *Evaluation of PRYSHM for LGBTQIA2S+ Youth*

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Statistical Design and Power

Power Analysis (Aim 2c). We understand that there are concerns about relying on small pilots in determining the potential promise of a new intervention. In this study, our primary objective will be to evaluate initial effect sizes in preparation for a Stage II RCT. We are using an intent-to-treat (ITT) approach to our analyses to retain all randomized cases, improve power, and reduce bias. The power analysis for our primary outcomes (i.e., AU, DV perpetration and victimization) utilized G*Power analysis protocols, including an equal allocation to conditions (assumption of equal groups; group allocation proportion = 1), a standard Type I error rate of α = .05, power (1-β) = .80. With a proposed sample size of 75 youth per arm (a realistic sample size for an R34 mechanism; total $N_{retained}$ = 150 from 200 enrolled), starting with a prevalence rate of 24%, we will be able to detect a meaningful reduction in DV rate (measured by the odds ratio of the % decrease in DV rate = .49; .45 prevalence rate ratio difference between conditions). With our proposed sample, for our continuously measured primary outcomes (e.g., AU), we will be able to detect a minimum difference between conditions with an effect size of 0.33 or more (a moderate effect). The effect size is supported by meta-analytic work on brief alcohol interventions (average effect size with Timeline Followback measure = 0.50; effect size across all measures = 0.25.[187]

Proposed Analyses (Aims 2c and 2d).

Preliminary *analyses: Validity checks.* To address a potential threat to internal validity, we will check the efficacy of the randomization procedures with the goal of creating equivalent groups. We will examine baseline equivalence on demographic characteristics and for each outcome domain (i.e., intermediate, primary, and secondary outcomes) between the experimental conditions using multivariate analysis of variance (MANOVA) for continuous variables and chi-square analysis for dichotomous outcomes. This will be completed for each analytic sample. Differences less than or equal to 0.05 standard deviations (*SD*) will be the criterion for satisfying the baseline equivalence requirement. To address any threats to internal validity due to inequivalent groups at baseline, we will account for any differences (> 0.05 *SD* in absolute value) between groups by including baseline measures (covariates) that require statistical adjustment in analyses approaches.

Differential attrition. We will guard against differential attrition by experimental condition as a potential threat to internal and external validity. We will track and examine if attrition rates differ for the experimental groups. We expect similar rates of attrition across experimental groups. Furthermore, we will use an intent to treat (ITT) analytic approach (i.e., use data from all cases of our randomized sample, who will all have baseline data based on our design) in our analyses to limit the bias introduced by missing data. We will conduct Little's[188] missing completely at random (MCAR) test and Simonoff's[189] regression diagnostic procedures to determine whether overall participant nonresponse meets the missing at random (MAR) assumptions required by the proposed analytic framework. Missing data assumed to be at least MAR will be dealt with as a function of the data analytic process through maximum likelihood estimation (ML),[190] which makes use of all available data and does not require deletion of incomplete cases, producing less biased estimates while retaining power.

Primary analyses: Aim 2c efficacy. We will use the rigorous intent-to-treat (ITT) approach (i.e., all participants randomized will be included in analysis) in all primary analyses. For the primary outcomes of DV perpetration and victimization, we will use logistic regression models within the context of structural equation modeling (SEM) to estimate the differences between the intervention group and wait-list control group, adjusting for pertinent demographic variables. The effects of interest are prevalence rate ratio differences between experimental conditions at immediate post-test and 3-month follow-up, controlling for pre-test prevalence rates. For the primary outcomes of AU and for the intermediary and secondary continuous outcomes, we will use analysis of covariance (ANCOVA) models within the SEM framework to examine differences at immediate post-test and 3-month follow-up as a function of condition while adjusting for relevant demographic variables and pre-test levels of outcomes. We will evaluate our hypotheses by examining significance (*p*), odds ratios (for categorical outcomes), confidence intervals, and the standardized difference between groups (*d*).

Exploratory analyses: Aim 2d moderation/mediation. We will examine how dosage, facilitator, gender identification, and other demographic variables may moderate treatment efficacy. Continuous moderators (e.g., dosage) will be operationalized as cross-product interactions with condition (all variables mean-centered) within the context of the SEM models. Significant interactions will be probed via estimation of +1*SD* and -1*SD* simple slopes. For dichotomous moderators, we will estimate SEM (i.e., either logistic regression or ANCOVA) and multiple group models, first allowing estimation of the path coefficients to vary freely across groups, and then constraining paths to be equal when a structural path coefficient of interest was significant for one group

and not the other group. We will conduct model comparisons using the chi-square (χ^2) difference test (i.e., χ^2, $p < .05$ indicating moderation). We will also examine whether the effect of treatment on outcomes can be explained by our mediators (intermediary outcomes). Evidence of mediation will be determined using the product of coefficients method, using parametric bias-corrected bootstrapping with 1,000 resamples to calculate the confidence intervals (CI).[191] All models will be evaluated for overall model fit via χ^2 statistic, root mean square error of approximation (RMSEA ≤ .08), the comparative fit index (CFI ≤ .08), and the Tucker-Lewis Index (TFI ≥ .90), as well as the significance and directionality of included path coefficients.