

Clinical Trial Consent Form Cover Sheet

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Project Title: Development and Evaluation of an Indigenized Family Acceptance Project for Lakota LGBTQ2S+ Youth

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Power and Statistical Design

Power Analyses (Aim 2b, 2c, and 2d). The primary focus of the current study is on program development/adaption, feasibility, and acceptability, and on identifying preliminary program impact on outcomes. Thus, the number of participants was, in part, chosen to address this primary focus. A secondary focus is on hypothesis testing. We propose an intent-to-treat (ITT) analytic approach that retains all randomized cases to improve power and reduce bias to provide a conservative test of program impact on outcomes. A power analysis was conducted using G-Power 3.1 power calculation program¹¹⁹ and the a priori *F*-test analysis of covariance (ANCOVA) routine for continuously measured outcomes (e.g., caregiver accepting behaviors) and the logistic regression routine for categorical outcomes (e.g., sexual violence victimization). These power analyses were conducted to understand the size of effects that can be detected with the proposed sample size ($N=60$ dyads).

For *continuous outcomes* (all intermediary and primary outcomes), our power analysis assumed a standard Type-I error rate of $\alpha = 0.05$ using the ANCOVA (fixed effects, main effects, and interactions) routine to examine outcome differences at post-test and follow-up among two experimental conditions, and the statistical benefit of one covariate (baseline measure of outcome variable). A sample size of $N=60$ families with power $(1-\beta) = 0.80$ results in a moderate minimum detectable effect size (MDES) $d=0.74$ ($f=0.37$). Our prior work with an open trial with SGMY online intervention suggests decreased youth internalized homophobia ($d=.80$)¹²⁰. For *categorical outcomes* (all secondary outcomes), our power analysis assumed a standard Type-I error rate of $\alpha = 0.05$ using the logistic regression routine. Using an incidence rate of .51, our proposed sample size ($N=60$ dyads) provides power to detect a minimum OR=.24.¹²¹

Proposed Analyses (Aim 2b, 2c, and 2d)

Preliminary Analyses: Baseline equivalence. To check for effective randomization with the goal of creating equivalent groups, we will examine baseline equivalence on demographic characteristics and for each outcome domain between the experimental and waitlist control conditions using multivariate analysis of variance (MANOVA). Results of the MANOVA suggesting differences less than or equal to 0.05 standard deviations (SD) satisfy the baseline equivalence requirement. We will account for any differences (> 0.05 SD in absolute value) between groups by including baseline measures (covariates) that require statistical adjustment in the primary outcome analyses of covariance or regression approaches.

Preliminary Analyses: Differential attrition. We will guard against differential attrition by experimental condition. We will track and examine if attrition rates differ for the two groups. We expect similar rates of attrition across 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's¹²² MCAR test and Simonoff's¹²³ regression diagnostic procedures to determine whether overall participant non-response meets the 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),¹²⁴ which makes use of all available data and does not require deletion of incomplete cases.

Preliminary Analyses: Nesting. We will examine the role of nesting within the treatment group, as individuals will be randomized to groups of dyads who will receive the intervention together (i.e., calculation of intraclass correlations [ICC] based on group assignment and facilitators in relation to outcomes). If needed, the role of group clustering will be accounted for in all analyses by implementing the outcome analysis using the ANCOVA framework within a mixed model with random effects for both conditions.¹²⁵ Related to the parent-youth family nesting, dyadic data analytic techniques will be utilized accounting for nesting of youth and caregivers by using the family as the unit of analysis within the structural equation modeling (SEM) framework.¹²⁶ For family process measures, we will create statistical indices of dyadic-level processes (e.g., mutuality, reciprocity, discrepancy) and examine intervention effects using these family-level indices.¹²⁵

Impact Analyses (Aims 2b, 2c, 2d). The effects of the program (experimental condition) will be assessed using an intent-to-treat approach (i.e., all participants enrolled and randomized to condition will be included in analyses using all available data) using ANCOVA or logistic regression in a SEM framework, with family as the unit of analysis. The effects of interest are quantified as differences between experimental conditions at post-

test and follow-up on proposed outcomes: caregiver accepting behaviors, youth and caregiver connection to Lakota culture, family bonding, and youth future orientation and decreases in caregiver rejecting behaviors, caregiver harsh parenting, and youth internalized homo/bi/transphobia (Aim 2b); primary outcomes (depressive symptoms, anxiety symptoms, suicidality) (Aim 2c); and secondary outcomes (alcohol and drug use/initiation and dating and sexual violence victimization and perpetration) (Aim 2d). These effects indicate whether the outcomes in the treatment condition differ significantly from those in the wait-list control condition. Experimental condition is the independent variable. We will include pertinent covariates (e.g., pre-test measurement of outcome of interest; method of survey completion) in all models. At pre-test, we expect that the difference between the experimental conditions to not differ significantly from zero, reflecting effective randomization. At post-test and follow-up, we expect the difference between the experimental conditions to be significantly greater than zero, reflecting better outcomes after the intervention period for those in the experimental condition. To reduce experiment wise error, we will estimate separate models based on constructs as presented in our Aims, including multiple related dependent variables with correlated errors. Models will use full information maximum likelihood estimation to account for missing data. For outcomes that are categorical (e.g., sexual violence victimization and perpetration), we will use logistic regression as estimated in SEM.

Models will be evaluated for overall model fit via χ^2 statistic, root mean square error of approximation (RMSEA $\leq .08$), the comparative fit index (CFI $\leq .08$), and the Tucker-Lewis Index (TLI $\geq .90$). We will evaluate our hypotheses across several indicators, including effect sizes (d =standardized difference between conditions; OR =difference in odds between conditions), precision of effect sizes (95% confidence intervals), directionality of included path coefficients, and significance (p).¹²⁷ The impact of contamination on the control group will be examined through sensitivity analysis. Given efforts to reduce contamination, we expect it to have a limited effect.