Journey of Transformation Curriculum for Native American Adolescents (JOT)

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Statistical Analysis Plan

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Statistical Design and Power

This study will evaluate the following primary outcomes: (1) alcohol, tobacco, and other drugs (ATOD; intentions to use, overall use, susceptibility, refusal self-efficacy) and (2) sexual and reproductive health (sexual activity, sexual self-efficacy, safer sex intentions). An intent-to-treat approach will be used to estimate the magnitude and statistical significance of intervention effects at immediate post-intervention. Each outcome will be evaluated in a separate generalized linear mixed model to evaluate the effect of CHJOT curriculum on intervention outcomes. Continuous outcomes will be modeled using a Gaussian link function for normally distributed data and binary outcomes using a logit link for Bernoulli-distributed data. The following equation represents the basic model for the outcomes: $\text{Outcome}_{tij} = b_0 + b_1\text{Intervention}_i + b_2\text{Time} + b_3(\text{Intervention}_{ij} \times \text{Time}_{tij}) + u_{0i} + r_{0ij} + e_{tij}$, where *t* indexes assessment, *i* indexes individual, and *j* indexes classroom. The last three terms on the right side of the model equation represent the variability between classrooms (u_{0j}), between individuals within classroom (r_{0ij}), and residual error (e_{tij}), respectively. The statistical test of the CHJOT curriculum will be the Intervention by Time interaction, which will evaluate whether recipients of the intervention curriculum improved more or decreased less from pre- to 2-month post-intervention compared with waitlist control.

To estimate the necessary sample size for our Longitudinal Mediation Model. We assume 80% power to detect a small intervention effect of d = 0.22 (standardized mean effect) of CJT (immediate intervention) vs. Waitlist control in pre-intervention to 3 month post-intervention outcome change. We base our power analysis on a repeated measures ANOVA design evaluating the Intervention by Time interaction in the primary outcome analysis, assuming a Type I error rate of 5%. Assuming a moderate temporal stability (r = .25) of the outcome measures, which is reasonable given the short interval between assessments, post-baseline data from 255 participants will be necessary to detect an intervention effect equivalent to a Cohen's d as low as 0.20, which would accommodate a 10% reduction in the observed intervention effect due to potential early exposure of control participants to the intervention (i.e., contamination effects). We anticipate a modest attrition rate of 15%, as the intervention will be offered in a required class in a boarding school indicating an analytic sample of 216 participants. Thus, our planned recruitment of 255 participants will provide a sufficient sample to detect targeted intervention effect, after accounting for attrition.