ClinicalTrials.gov Data Entry Cover Sheet

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Project Title: *The Impact of an Adapted Version of the Strengthening Families Program on IPV Among Caregivers and ACEs Among Children*

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Statistical Design

Data Analysis (Survey Data) *Preliminary Analyses.*

Baseline equivalence. To 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 between the experimental conditions using multivariate analysis of variance (MANOVA). 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. 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 of covariance or regression approaches.

Nesting. We will also examine the role of nesting within the treatment group, as individuals will be randomized to groups of families who will receive the intervention together (i.e., calculation of intraclass correlations [ICC] based on group assignment and facilitator in relation to outcomes). If needed, the role of group clustering will be accounted for in all analyses.

Differential attrition. We will guard against differential attrition by experimental condition. 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 intentto-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[171] MCAR test and Simonoff's[172] 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),[173] which makes use of all available data and does not require deletion of incomplete cases.

Psychometric analyses. For measures that have been used previously, scale reliabilities will be evaluated for comparability with prior literature using Cronbach's alpha coefficients based on pre-test data. For measures that have not previously been used with this population, psychometric work will be conducted. Confirmatory factor analysis (CFA) will be used to evaluate the hypothesized factor structure using pre-test data. The first stage of the analysis will fit factor models to evaluate the factor structure as compared to theory. To estimate the CFA, we will use the common factor model and full information maximum likelihood-robust (FIML-R) estimation within a structural equation modeling (SEM) framework[174] using Mplus. To determine the best fitting factor model, we will evaluate the fit of the model using multiple indices (i.e., χ^2 test statistics, RMSEA < .08; SRMR < .08; CFI > .96174). Based on the psychometric work, adjustments to the measures will be made as necessary. Lastly, we will examine internal consistency estimates of Cronbach's reliability of these measures, when applicable.

Outcome Analyses.

Aim 2c. The effects of Was'ake Tiwahe program (intervention condition) on youth, caregiver, and family intermediary, primary, and secondary outcomes will be assessed using an intent-to-treat approach (i.e., all participants randomized will be included in analysis) within the

ANCOVA framework. The effects of interest are differences between experimental conditions at post-test and follow-up on youth, parent, and family outcomes, as detailed in the logic model (Research Strategy, Figure 1). These effects indicate whether the outcomes in the intervention condition differ significantly from those in the wait-list control condition. The experimental condition is the independent variable in these models. We will include pertinent covariates (e.g., pre-test measurement of outcome of interest, cohort, youth gender) in all models. At pre-test, we expect that the mean difference between the experimental conditions will 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 Was'ake Tiwahe program condition. If nesting is of concern based on preliminary ICC analyses, we will implement the outcome analysis using the ANCOVA framework within a mixed model with random effects for both conditions.[175] We will evaluate our hypotheses by examining significance (p), confidence intervals, and the standardized difference between groups (d).[176]

Aim 2d. Structural equation modeling (MSEM) will be utilized via Mplus software to test whether the intermediary outcomes (child, caregiver, and family outcomes) at post-test are at least partial mediators of the effect of the program on the primary outcome of youth ACEs at follow-up and whether there are moderators of the effect of the program on youth ACEs. Evidence of mediation will be determined using the product of coefficients method[177] using parametric bias-corrected bootstrapping with 1,000 resamples to calculate the confidence intervals (CI).[178] To test for moderation for dichotomous variables (e.g., gender), we will estimate SEM 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). For continuous moderators, they will be operationalized as cross-product interactions with condition (all variables mean-centered). Significant interactions will be probed. [179] 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 (TFI $\geq .90$), as well as the significance and directionality of included path coefficients. Nesting will be accounted for, as needed.