Title: Testing a Brief Substance Misuse Preventative Intervention for Parents/Guardians of 5th-7th Grade Students

NCT Number: NCT03925220

Statistical Analysis Plan

Document Date: August 10, 2023; Revised: November 11, 2018

Data Analysis Plan

The scientific rigor of this application is reflected in our preliminary analyses, missing data detection and correction procedures, and our data analytic strategies. First, all forms will be checked for missing data and outliers prior to data entry. Attrition effects will be evaluated by testing whether systematic differences exist between participants who complete the research versus those who drop out. We will also examine any pre-existing differences between the two conditions in demographic composition and all measures collected at baseline. Pre-existing group differences in these variables will be accounted for in subsequent analyses, using baseline scores as covariates. Participants will be included in the analysis if they are randomized (i.e., intention -to-treat). Participants who are lost to follow-up or drop out can affect the validity of the group comparisons if: 1) the outcome of interest is related to being lost or dropped, and 2) it is differential between groups. The missing data mechanism will be formally tested to determine whether it is Missing Completely at Random (MCAR) or Missing at Random (MAR). For completeness in assessing the effect of missingness, two additional analyses will be conducted: 1) a 'per-protocol' analysis among participants who complete all follow-up surveys; and 2) multiple imputation of five data sets using a discriminant function for binary outcomes and Markov chain Monte Carlo for continuous outcomes, assuming the missing data mechanism is MAR.

Aim 1: To determine the efficacy of the brief intervention on parent outcomes. The proportion of parents who more frequently communicate will be compared between conditions across the follow-up periods using a repeated measures log-binomial regression analysis (via generalized estimating equations; GEE), with an appropriate covariance structure and adjusting for baseline scores. Covariates will be added to the modeled analyses if differences among baseline characteristics are observed. A test for interaction between condition and follow-up point using the above models will assess whether there is a differential intervention effect across time, taking intervention dose delivered and received into account. To assess quality of mealtime interactions, we will first score the videos according to the IFIRS and then analyze the data using repeated measures analysis of covariance (i.e., a linear mixed model) to compare the two conditions across the follow-ups, using an appropriate covariance structure and adjusting for baseline scores. A similar analysis will be used for the summed scores from the FAsTask, which assess the quality of parent-child conversations about SU.

Aim 2: To examine the effects of the intervention on child SU beliefs, intentions, and willingness, and affiliation with substance-using peers. We will compare the proportion of children with intentions and willingness to use substances, negative SU attitudes and expectancies, and substance-using peers between conditions across the follow-up periods using a repeated measures log-binomial regression analysis (via GEE), with an appropriate covariance structure and adjusting for baseline scores.

Secondary Aim 1: To examine the effects of the intervention on SU initiation. To assess whether children of parents in the intervention condition delay the initiation of SU longer than the comparison condition, we will compare the incidence of initiation using a

discrete-time survival analysis via a complementary log-log regression model, as the date of initiation between follow-up time points may not be known exactly.

Exploratory analyses will be run by race and ethnicity. Because it is known that subgroup analyses have less statistical power than the primary analysis, we will conduct exploratory analyses to determine whether the efficacy of the intervention varies by race and ethnicity, to inform future adaptations.