

Study Protocol and Statistical Analysis Plan

Brief Title: Feasibility of a web-based program to help parents of middle school students effectively communicate with their children about substance use

Protocol ID: Middle Years Study R21-23-003-001

ClinicalTrials.gov ID: NCT05900115

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The purpose of the project, is to evaluate and assess a self-administered, web-based program, Media Ready Parent (MRP), designed to increase parent knowledge about adolescent substance use, active media mediation skills, and practice high-quality parent-adolescent communication methods. The program will help parents of middle-school aged students, 6th-8th graders, communicate effectively about substance use and enhance media literacy skills to counter unhealthy media messages. Prevention efforts are most impacting for adolescents in middle school years as this is the time frame for growing independence, desire to fit-in and an increase risk for their own experimentation with substances.

The procedure that will be used for conducting the research study is as follows:

1. We will aim for 286 parent-child pairs (child in 6th, 7th, or 8th) to participate in this study. We will aim to have the sample consist of at least 40% fathers or male guardians and no more than 60% white non-Hispanic adult participants. Parent-child pairs will be stratified by parent's gender and race/ethnicity prior to randomization to ensure diversity across groups.
2. A recruitment website will be available. Interested parents can complete an online screener found on the website. If eligible, parents will be directed to a place where parents and their children can complete the online informed consent process. The study team will enroll eligible, consented pairs based on whether there is room in the study according to gender and race/ethnicity stratification. If there is space in the study, parent-child pairs will be randomly assigned to either condition 1) Media Ready Parent (intervention) or 2) active control (i.e., medically-accurate information from sources like the CDC about adolescent substance use).
3. Pretest questionnaires for parents and their children will be distributed to enrolled parents in two separate emails/texts containing a link to complete their respective questionnaires. Participants will have one week to complete their questionnaires. If both the parent and child complete their questionnaire, they will be eligible for a \$30 gift card.
4. Parents will receive a reminder (email, phone call, or text) to complete the pretest questionnaires if both are not completed in the first two business days. If both questionnaires are not completed, the parent will receive a final reminder around the 6th day. See Appendix E for automated messages.
5. Once pretests questionnaires are completed, parents will receive a link to access their randomly assigned resource. The resources could take up to 2 hours to review. Parents will be asked to completely review their assigned resource within two weeks. If they do so, they will be eligible for a \$25 gift card. However, parents will have access to their assigned resource for four weeks (until the posttest questionnaire). Parents will receive a reminder after one week of receiving access to their resources to complete their review within the following week. Parents will receive a final reminder on about the 13th day to complete their review of the resource.
6. About four weeks after pretest questionnaire completion, parents will receive two emails/texts – one with a link to their posttest questionnaire and one with a link to their child's posttest questionnaire. Participants will have one week to complete their

questionnaires. If both the parent and child complete their questionnaire, they will be eligible for a \$50 gift card.

7. Control participants will receive access to MRP after study is completed to review as desired.
8. Incentives will take the form of gift cards. Participants will be able to choose between Amazon and Walmart gift cards. We will mail incentives to participants' physical address after pretest completion (max \$30) and after posttest completion (max \$75).

Statistical Analysis Plan

Preliminary Analyses. Psychometric analyses will be conducted to confirm the reliability, validity, and distributions of key variables. To establish if there is baseline equivalence between groups, we will test for equivalence on basic demographic characteristics (i.e., age, race/ethnicity, gender, and sexual orientation) and on baseline levels of our primary outcome variables in a series of t-test and χ^2 analyses. If we establish that the intervention and control groups are not equivalent on any pre-specified variables, these variables will be used as covariates in the analyses of intervention effects. Missing data will be handled using multiple imputation methods.

Main Analyses. To examine intervention effects on primary outcomes at posttest, we will use a series of linear and logistic regressions in intent-to-treat analyses. For outcomes that have only one informant, posttest scores will be regressed onto pretest scores, covariates, and the treatment effect. Covariates will include parent gender, youth gender, youth age, parent substance use, SES, and supportive parenting.