STUDY PROTOCOL AND DATA ANALYSIS

The Rewire Study (Mindfulness Mobile App to Reduce Adolescent Substance Use)

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STUDY PROTOCOL

We will conduct a pilot test of the My MUSE app with 60 high-risk adolescents who are involved in the juvenile justice system. Feasibility, usability, participant satisfaction, and pre-/post- intervention outcomes of substance use will be evaluated in the pilot study. Data on: 1) frequency and duration of app use, 2) number of modules completed, and 3) type and frequency of substance use pre- and post-intervention will be examined. Participants will be compensated using gift cards to Amazon in the following increments: $20 for each of the baseline, 6 week and 3-month assessments, and $25 bonus for completion off all three assessments. Participants in the focus groups or usability testing will receive a $35 gift card for their time and effort.

Participants will include both male and female high risk adolescents recruited from the Department of Youth Services (DYS) in Lane County, Oregon. We have a long history of successful collaborations with the DYS, and have received their support for the current proposal. Inclusion criteria will be as follows: 1) ages 13-17, 2) involvement with the juvenile justice system, 3) documented substance use, 4) English-speaking, and 5) living in the community (e.g., biological/ adoptive/foster parents). Twenty of these high-risk adolescents will be recruited to participate in two focus groups to give us initial reactions to mockup of modules; five of these participants will also be asked to participate in preliminary usability testing of the first 4 modules of the MyMUSE app. Feedback from focus groups and preliminary usability testing will be used to inform adaptations to the app. The prototype app will then be evaluated in a pilot testing phase by having 60 additional high-risk adolescents complete the 4 adapted treatment modules over the course of 6 weeks. Usability data, system log data on program use, and participant satisfaction data will be analyzed, and input gathered from participants will be used to inform additional features to be developed during Phase II. The primary outcomes of the pilot-testing phase will be changes in adolescent substance use attitudes and behaviors measured at three time points: baseline, 6 weeks post-baseline (end of treatment), and three months post-baseline.

Program navigation and usability will be assessed during usability testing and for the evaluation participants over the 6 weeks of use, and will include reports of: 1) ease of use, 2) perceived benefits of using the app, and 3) suggestions for product development and modifications. Participants will also provide ratings on product satisfaction and usability on a 7-point Likert Scale. Qualitative data gathered from the focus groups will be recorded and evaluated with the goal of identifying challenges to using the app, product satisfaction, and suggested product modifications. This information will then be used to guide modifications for a Phase II SBIR application. In addition to qualitative data gathered during the pilot evaluation study, login tracking information from the app will be used to assess each participant's: 1) frequency and duration of app use, 2) number of modules completed, and 3) type and frequency of substance use. These data will be used to evaluate treatment engagement and adherence, as well as to inform possible changes in substance use pre- and post-baseline.

The following measures will be used to examine changes in pre- and post- changes in substance use: 1) Alcohol and Drug Use Survey, 2) Adolescent Attitudes Questionnaire, and 3) Emotion Regulation Scale. The Alcohol and Drug Use Survey is a 48-item scale that combines the Michigan Alcohol Screening Test (MAST) and the Drug Abuse Screening Test (DAST) and the Self-Efficacy for Limiting Substance Use. These scales are widely used as measures to assess the level and frequency of alcohol and drug use, as well as the ability to limit substance use, and have been shown to have good psychometric properties. The Adolescent Attitudes Questionnaire is a measure of attitudes and beliefs regarding drug and alcohol that was adapted from an interview developed to test 12 mediators of drug use in adolescents. For this study, we will use the normative beliefs, lifestyle incongruence, beliefs about consequences, and commitment scales. The Emotion Regulation Scale is a 36-item self-report questionnaire designed to assess multiple aspects of emotion dysregulation.

STATISTICAL ANALYSIS PLAN

Outcome Evaluation. A three-panel, pre-, six week post-training, and three month follow-up design will be employed to assess the feasibility of the MyMUSE app. During this non-experimental trial phase, consumer satisfaction ratings will be assessed and recommendations for program modification will be solicited from the program participants. We will also examine system log files to assess participant engagement in using the app (e.g., program components viewed, number of visits, and time of use). While the design does not control for potential threats to internal validity (i.e., extraneous factors), it will allow for the evaluation of the app with respect to change on adolescent substance use attitudes and behaviors. Threats to internal validity will be addressed during a large–scale SBIR Phase-II randomized controlled trial comparing adolescents assigned the MyMUSE app versus a wait-list control group.

Data analysis. Prior to analysis, all variables will be checked for out-of-range values and inter- and intra-measure consistency; frequency distributions and plots will be examined for unusual data distributions or data points. Any necessary data transformations will be employed. The main analysis will test the hypothesis that participants will show significant improvement in emotional and behavioral changes and attitudes and beliefs regarding substance use. We will use random coefficient growth models in a multilevel framework with individual variability in change in study outcomes from pretest to 3-months nested within individuals. Following Singer and Willet [49] when constructing the longitudinal model we will (a) examine empirical growth plots; (b) fit an unconditional means model; (c) fit an unconditional linear growth model; (d) fit unconditional non-linear models; and (e) compare models of longitudinal change from the previous two steps using the Akaike Information Criterion. To bolster our confidence in the internal validity of the non-experimental design, some ancillary analyses will be conducted. First, a dose-response analysis based on program system usage log files will be conducted to determine whether the amount of program use (e.g., program components viewed, number of visits, and time of use) is significantly associated with change in the outcome measures. Residual gain score analyses will be conducted using linear regression models to predict post-training and follow-up test scores in which the pre-training test scores will be included as a covariate. Second, we will test the hypothesis that participants who report greater satisfaction with the training app will have greater improvement in pre-training to post-training and follow-up scores using residual gain score analysis. Finally, treating consumer satisfaction as a process variable, we will examine correlations between the satisfaction ratings and the amount of program use. To the extent that there is sufficient variability in program use and consumer satisfaction, positive associations between these measures and change in pre- to post-training and follow-up scores will provide further support for the acceptability and effectiveness of the training app.

Missing data. Missing data in outcome measures may result from dropout or item non-response. The mixed-growth models described above make use of maximum likelihood estimates and allow for use of all available outcome data from all assessments, reducing bias and increasing power [50]. In general, maximum likelihood procedures, as well as imputation methods, will be used as they can provide unbiased estimates even in instances of substantial attrition [50-51]. Multiple imputation procedures will follow best-practice recommendations [52] and the observed and imputed data will be compared to ensure they show similar distributions [53].

Power considerations. We rely on the fact that power from random coefficient growth models have been shown to surpass that of a mixed-model ANCOVA [54-55]. We based the power analysis on the mixed-model ANCOVA, thus providing a conservative estimate for random coefficients growth models. Based on a sample size of 60 participants, a two-tailed alpha at .05, a moderate correlation between pretest and posttest scores (R^2 = .25) we have sufficient power (>.80) to detect moderately small effects or greater (d = .39). Analyses involving correlation coefficients will have adequate power to detect medium effects (r = .35).