TITLE: Testing an Arts-based Program to Reduce Nurse Stigma Towards Perinatal Substance Use

NCT NUMBER: NCT06410287

VERSION DATE: 6/13/24

STATISTICAL ANALYSIS PLAN

Analytic Plan: Descriptive statistics (means, medians and interquartile ranges for continuous variables, and counts and proportions for categorical variables) will be used to characterize the demographic characteristics of our sample.

Intervention Feasibility and Acceptability: Our primary analyses will assess feasibility of DAB-RN as a whole. The analysis will examine the feasibility of the intervention (ie, proportion responding to and completing the intervention; participant satisfaction; ability to deliver the intervention with fidelity; and costs to deliver) using univariate descriptive statistics (proportions, means, and ranges) and by comparing differences by unit, years of experience, race/ethnicity, and age, using t-tests for continuous variables and test for the difference in proportion for binary variables. To inform a future efficacy trial, we will monitor recruitment and retention rates, using the following retention cut-off percentages to assess feasibility: a) 90+ = strong feasibility; b) 80-89% = good feasibility; c) 70-79% = acceptable feasibility; d) 60-69 = moderate feasibility but requires improvement; e) <60% = unacceptable. We will explore recruitment and retention by gender, race, age, and experience to examine the ability to recruit a diverse sample that reflects the population of nurses caring for mothers and infants affected by perinatal opioid use.

Secondary analysis: Explore unpowered changes in stigmatizing attitudes. The change in stigma score will be analyzed at 2 points in time: 1) immediately following completion of the intervention, only within the experimental arm, and 2) at 3 months between the experimental and control arms. We will test the immediate change using a paired t-test of the hypothesis that the change in score is different from zero within RNs who received the intervention. We will test the change at 3 months using an independent t-test of the hypothesis that the difference over time between the experimental group and the control group is non-zero. In addition we will develop a regression model for the change in stigma score as a function of covariates such as unit, age, and race. An indicator variable for the experimental arm will be used to test the difference between the groups, controlling for the other covariates. Stepwise selection will be used to identify variables that are most strongly and independently associated with the change in stigma scores. For all hypothesis tests, we will report p-values and a threshold of .05 will be used to determine significance. We will also examine the difference in distribution of stigma score before and after the intervention using the Kolmogorov-Smirnov test. This non-parametric test for distributions does not require assumptions about the shape of the underlying distributions. To visualize the test results, we will construct box plots of the attitude scores at each point of time by intervention group.

Sample Size Justification: The sample size for this feasibility study (n=75 per group; n=150 total) is consistent with recommendations of sample sizes for pilot studies of this nature.[102-103] As a pilot study, our power calculation focuses on only a few outcomes and leaves room for uncertainty in our assumptions. We based our sample size estimates on detecting a moderate effect size of 0.5[113] which we believe is a meaningful difference for these pilot data and is informed by our previous pilot study testing a different version of the intervention. Assuming 75 participants in each group, and test performed at alpha level of 5%, the between-group tests would have power of 86%, and the paired t-test for immediate change in stigma score would have power greater than 90%. The 3-month differences will be unpowered at a moderate effect size; however, these pilot data will provide us with an estimate of attrition. In addition, estimates of attrition, effect, and correlation will be needed to power a future multisite cluster-randomized study evaluating the intervention's efficacy.