The Effect of Live Music Therapy Interventions with Pediatric Patients who are Mechanically Ventilated and Sedated

November 20th, 2017

Study Protocol and Statistical Analysis

The music therapist will introduce self to the patient's caregiver at bedside to discuss study. After obtaining consent, the caregiver-patient dyad will be assigned to either the live music therapy group or control group in an block randomization. Caregivers in both groups will be asked to complete the Parental Beliefs Scale for Hospitalized Children (PBS) prior to the intervention and baseline child measures (HR, MAP, RR) will be collected. Both interventions will be provided at bedside and post intervention child measures will be collected immediately following the intervention. The participants will be thanked for participation in the study and provided with a CD as well as ways to incorporate music at home to support development for their participation in the study. Child measures will also be collected 30 minutes and 60 minutes post intervention for both groups in their electronic medical record. Caregivers will be asked to complete the PBS 60 minutes following the intervention.

Both interventions will be conducted in the child's primary language (English or Spanish). Spanish songs were identified by hospital employed medical interpreters. The control group CD will be recorded by the principal investigator utilizing guitar and voice with the exact songs utilized in the live music therapy intervention. The recording will be completed at a music studio in Atlanta to assure a high quality recording for the control group.

Data Analysis Procedures

Patients will be measured at 4 time points: prior to intervention, immediately post intervention, and 30 minutes and 60 minutes later. Because each subject is measured multiple times,the data will be analyzed using a repeated measures analysis of variance model. Each condition will be compared to baseline to determine the relative effectiveness and sustainability of the intervention (i.e., effect at 1 hour). Changes in parental efficacy will be determined using

paired t-tests of Wilcoxon signed rank tests. Data will be described using means and standard deviations, counts and percentages or medians and ranges, as appropriate. Difference in means between time points will be further quantified using 95% confidence intervals. Analysis will be conducted using SAS v. 9.4 and statistical significance will be assessed at the 0.05 level. Given the sample size of 24, there is sufficient power (>80%) to detect at least a 5 point decrease in HR and MAP from baseline.