Katharine Press
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IRB Write-Up for CRC

Title of Project: Parent Stress in the Cardiac NICU and the Effect of BACI, a Supportive Intervention

Study Purpose and Rationale:

The study aim is two-fold: (1) to measure stress in parents in the cardiac NICU and see how it changes through the admission and (2) to evaluate the effect of the BACI program on parental distress in cardiac parents in the CUMC NICU. Our hypothesis is that the Neonatal Unit Parental Stress (NUPS) scale scores will decrease more in at the pre-discharge time point for parents who receive the BACI intervention compared with control parents in analyses controlling for neonate's medical condition and baseline parental factors.

Brief Background:

Parents of newborns admitted to the NICU are at high risk of both short and long term distress. A change in the role of parents, the neonate's behavior/appearance, and anxiety over decision making all play a role in the NICU parents' experience. This has been studied most extensively in preterm infants, while studies specific to neonates with cardiac anomalies are lacking. Infants with cardiac anomalies account for 1,000 live births each year and long-term studies of children with cardiac conditions reveal high levels of parental distress. Cardiac neonates are unique in a number of ways, with a large percentage requiring surgery soon after birth and many expected to have long term disease burden. Two preliminary studies have indeed found high rates of distress in parents of infants in the cardiac NICU. However, little is known about how stress changes over the admission and how it is correlated to demographic and support system factors.

A number of interventions have been found to be effective in reducing stress for NICU parents. These include programs that provide specific ways for parents to interact with infants, initiatives to educate parents and provide psychological support, and efforts to improve communication between NICU providers and parents. Such interventions have been found to have significant impact on parental experience as documented by several validated scales such as the NUPS (Neonatal Unit Parental Stress) scale and the Infant Parent Worry Index. However, to date no such interventions have focused on parents of cardiac infants.

The BACI program (Italian word for "kisses", here an acronym for Baby Attachment and Comfort Interventions) is ongoing in the CHONY NICU and will soon be introduced in the cardiac NICU. It is aimed at improving the baby's comfort and parent's experience. BACI is modeled after the Neonatal Comfort Care program's guidelines focused on the achievement of a state of comfort for the baby and the family. (1) It takes advantage of the infrastructure that is already part of the Neonatal Comfort Care program and apply it to newborns and families that are not pursuing strict comfort care. It includes interventions that address parent support, feeding, bonding, and memories/keepsakes.

Study Design and Statistical Analysis:

Patient Population: We will enroll newborns diagnosed with congenital heart disease (CHD) admitted to MSCHONY beginning June 1, 2017 through October 1, 2017. We will concurrently enroll their parents, aiming for up to 50 parents corresponding to 25 neonates in both the baseline group and in the BACI group. Thus the grand total will be up to 50 neonates and 100 parents. Final enrollment numbers will be decided on after baseline data is used to gauge power. Mothers and fathers of infants with CHD requiring NICU admission will be invited to participate. Families will be excluded if they are not fluent in English or the infants condition is so severe that they are not expected to survive.

Study Procedure: This is a cohort study utilizing questionnaires and qualitative questions. Families will be consented and will complete the attached demographic form. Parents will be asked to complete Neonatal Unit Parental Stressor (NUPS) scale and Depression, Anxiety, and Stress Scale (DASS-21) questionnaires within the first week of the newborn's life. The NUPS questionnaire was selected because it was developed to highlight particular issues causing stress for parents experiencing neonatal intensive care and thereby to inform the development of effective intervention strategies (Reid, Bramwell, Booth & Weindling 2005). We also plan to include the DASS-21, a self-report measure of overall symptoms of stress, anxiety, and depression, to gather information about parents' psychological state more generally (Lovibond 1995). If significant depression is revealed, we will refer to appropriate mental health services. DASS-21 alone cannot diagnose depression. As such, significant risk of depression will be defined as scores in the range of Severe or Extremely Severe per the DASS-21 questionnaire scoring guideline. Patients meeting these criteria will be treated the same way as any parents in the NICU in whom depression is suspected clinically. Specifically, parents will be referred to meet with either the on call social worker or psychologist for the cardiac NICU who will conduct a risk assessment. If deemed appropriate, they will be referred for further treatment in accordance with their insurance, but frequently to the Columbia Women's Health Program. Parents will be asked to complete the same questionnaires a second time and to answer four open-ended questions about their NICU experience in an open-ended written form. This will occur prior to discharge, or in the case of prolonged admission >1 month after admission when the infant is clinically stable. We have included qualitative responses as qualitative research permits elucidation of the experiences and perspectives of the under-researched populations. We will also access basic information from the newborn's chart to assess clinical severity. We will also review the medical record to see whether patients were enrolled in the BACI program.

Recruitment: Describe how participants will be recruited: The study team will regularly review the NICU cardiac team census and screen for eligible patients. The responsible primary care medical team in the CHONY NICU who will ascertain their willingness to discuss the study further with the members of the study team. At the identification, the study team will present information regarding this study and answer any questions parents may have.

Instruments: INCLUDE COPIES

Confidentiality of Study Data:

Paper files in a locked cabinet to which only PI can access with a key. The identifiers will be listed on a sheet that matches the identifier with the patient name. This sheet will be destroyed at the conclusion of the research. Only deidentified information will be entered electronically. The study data will be entered in anonymous form into a computer protected with a password known only by the study team.

Conflict of Interest:
No conflicts of interest to report.

Study Location:
CHONY NICU

Potential Risks:
The most significant risk posed by this study is psychological distress caused by reflecting on the stress of having a child with CHD while completing the questionnaire and interview. Additionally, there is a risk of breach of confidentiality given that personal data is being collected. However, we will make every effort to minimize this risk by appropriately storing and de-identifying data as described in "Privacy and Data Security."

Potential Benefits:
The direct benefits to participants is the opportunity to feel heard and the psychological support provided by having someone to talk to during the interview. The benefits to future NICU families is that we hope this study will inform continued development of more effective support programs in the cardiac NICU.

Compensation:
No compensation is required or provided for participation in this study.

Data Management:
Demographic data will provide patient population characteristics. Completed NUPS questionnaires will be evaluated to obtain subsection and overall mean stress indices. The DASS-21 questionnaires will be collated into sum scores for stress, anxiety and depression. Data from both questionnaires from both time points will be analyzed by SPSS software. Parents' comments to written questions will be transcribed and evaluated in a qualitative fashion and synthetic categories of common themes will be identified and assessed with NVIVO software.

Statistical Analysis:
Power calculations will be performed after we have collected baseline data from 25 subjects. At this point, we will be able to calculate the changes in NUPS scores, the primary outcome measure. Using standard deviations from these data and assuming that at least a 10% reduction in stress is necessary to deem the program clinically useful, we will calculate the number of subjects we need to enroll for adequate power.

Ultimately, we plan to analyze the data as follows. If two parents are enrolled for a single infant, we will average their test scores, so infants will be the unit of measure. We will then calculate mean change in NUPS score and DASS score. We will use T tests to compare between the two groups. We may also make a multiple regression model in which we can control for 2-3 demographic factors that are most predictive.